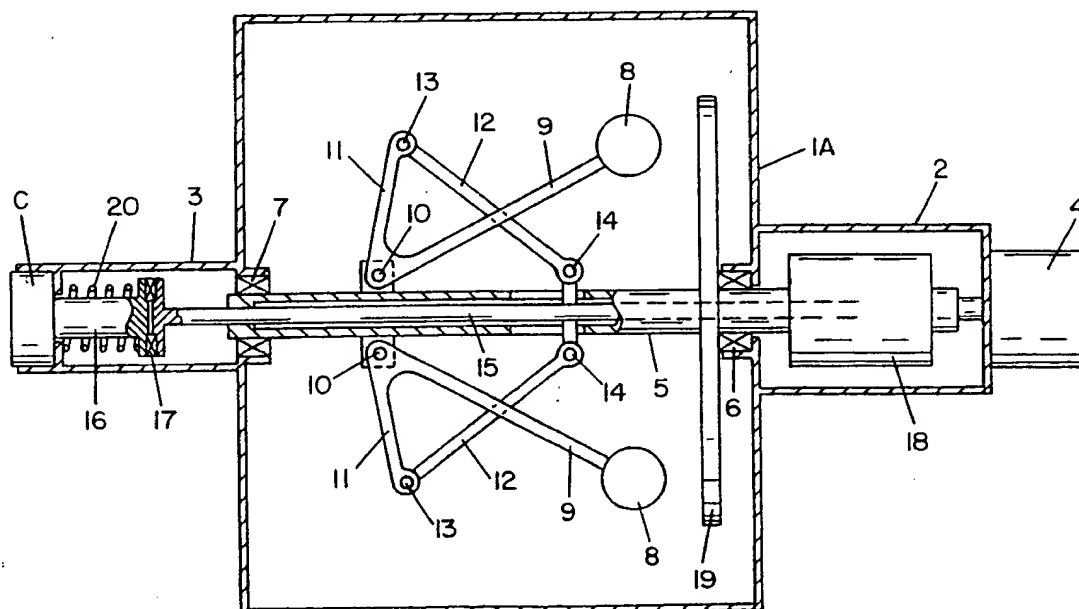




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(54) Title: HYPODERMIC FLUID DISPENSER



## (57) Abstract

This invention is a jet injector (1) for injecting fluid into a body. The jet injection system (703) includes capsules (820, 846) for holding the material to be injected, an apparatus (848) for applying force to the capsule(s) (846) to eject the injection material(s) and a perforator (882) for directing the jet stream for the respective materials into the body. A flyweight (8) system is described for developing injection pressures, and latching devices (18) control the flyweight (8) system. An injector system (840) for injecting more than one fluid is described.

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## **HYPODERMIC FLUID DISPENSER**

### **Cross-Reference to Related Application**

This application is a continuation-in-part of corresponding U.S. patent  
5 application Serial No. 08/253,416, filed June 3, 1994, which is a continuation-in-part  
of Serial No. 07/818,235, filed January 8, 1992, which is a continuation-in-part of  
Serial No. 07/336,636, filed April 7, 1989, which is a file wrapper continuation of U.S.  
Serial No. 07/059,620, filed June 8, 1987, now abandoned.

### **Background of the Invention**

#### 10 **Field of the Invention**

This invention relates to apparatus for the hypodermic injection of fluids.

#### **Description of the Prior Art**

Hypodermic fluid dispensers fall into two broad categories, namely, needle  
hypodermic dispensers and needle-less injectors, such as jet injectors. In the past, jet  
15 injectors have been particularly useful in large scale immunization programs, such as  
those administered by the World Health Organization (WHO) or the military, for  
example, where the number of subjects to be immunized in a single session is very  
large (more than 200 injections per session). However, in recent years, jet injectors  
are also finding benefit in more routine immunizations at WHO health centers around  
20 the world, where the number of subjects injected is relatively small at less than 40  
injections per session.

In general, jet inoculation, as compared to needle inoculation, is less traumatic,  
requires less operator training, and allows a higher number of procedures per unit of  
time.

25 Although both needle hypodermic injectors and high pressure jet injectors have  
been widely used, the presently known devices have serious disadvantages with respect  
to the injection of humans and animals alike. There exists a high level of belief that  
conventional jet injectors are capable of cross-infection when the same orifice is used  
for subsequent injections, and the problems associated with needle injectors in the  
30 spread of AIDS (Acquired Immune Deficiency Syndrome) alone is sufficient  
motivation to avoid proliferation of today's needle systems. People cannot be relied

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upon to dispose of needle injectors in accordance with instructions and good practice, and an element of the population are tempted to reuse needles without knowledge of or regard for safe practices.

5 There are other important shortcomings in the present state of the art with respect to the inoculation of humans and large animals, such as cattle and pigs. In the case of large animals, needles used for injecting vaccines, vitamins, medications and hormones in large, food-producing animals often cause damage to prime portions of the meat through the creation of abscesses and scars, resulting in serious economic loss to the industry. In the majority of cases, these factors are even more prevalent because  
10 the needle injectors become dull or bent when used for multiple injections, which is a common practice in the industry. In addition, due to increased awareness of cross-infection in food-producing animals, agricultural leaders recommend that needles no longer be reused for animal injections. Furthermore, it is not at all unusual for multiple injections to be scheduled within the same period of time, this being true for  
15 humans and animals as well. However, repeated injections are usually met with greater resistance by the recipient and also makes the procedure far more expensive. Hence, other important shortcomings would be overcome if more than one material could be injected at the same time.

Properly configured jet injectors provide the best chance for reducing the  
20 problems of cross-contamination, as well as the case where more than one injection is required at the same time, and could reduce the time to train people involved in the injection process. If jet injectors were effective for both animals and humans, a higher number of procedures per unit of time would be possible. The higher number of procedures is particularly important in the beef and dairy industry where each day a  
25 certain number of animals receive injections. This is also true for the multiple vaccine requirement for children.

Large animal hide, such as cowhide, can be very thick, often in the range of 1/8 inch to 3/8 inch or more in thickness. The hide includes the hair, a tough outer layer, and thereafter the dermis, whose inside surface has a rubber-like interface that  
30 begins the subcutaneous ("sub-Q") layer that separates the hide and the muscle. In cattle, injections are usually given in the neck, a leg or a hind quarter. A known CO<sub>2</sub>-driven jet injector was experimentally tested on a freshly euthanized cow and the

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injection site was immediately followed by a pathologist's examination. It was found that the injection rarely penetrated the desired depth into the muscle.

Electrically operated needle-less injectors, previously disclosed, often require batteries, since standard power sources are not available at remote or isolated areas where injections are often given. People responsible for the immunization programs at these locations are concerned about disposal of these batteries, leading to the recommendation that rechargeable batteries be used. Indeed, the use of any electrically-powered injector used away from standard power sources would be enhanced if there were no batteries to be disposed of, yet sufficient electrical power were available.

The exit path of needle-less injectors, referred to as "orifices," present additional problems. Orifices are commonly found in the range of .004 to .014 inches. Extensive experimentation has shown that these orifices are likely to be ineffective for deep injections unless virtually perfect in structure and optimized in diameter for that particular injection site. If the orifices are poorly configured, they will fail to penetrate the thick hide of an animal, and satisfactory deep injections will not occur no matter what pressure is applied on the serum or other product being injected. When poorly configured orifices with diameters in the range of .004 to .014 inches are used with injection pressures as high as 2,000 to 10,000 psi, effective deep injections have not been possible.

It is important that the speed at which needle-less injections are made is high, whereby the entire dose, or doses, enters the animal's body quickly by way of the high velocity jet stream. Movement could cause a loss of the initial penetration point and the injection could fail. As noted above with respect to cows, the injection must clear a hide thickness of 3/8 inch, or more in some cases, to achieve intramuscular ("IM") injection. Speed of injection, orifice size, quality of the jet stream, and lack of movement are necessary to get good IM injection results. If any of these characteristics are not fully met, or if the jet stream breaks down when the injection material is designed for an IM injection, the fluid will remain in the dermis, or in the subcutaneous layer instead, and could result in a less-effective or even a totally useless injection.

Presently known collapsible bodies or containers (generally referred to

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hereinafter as "containers") for holding hypodermic fluid do not readily provide the necessary fluid even when sufficient pressure is applied to the collapsible container. Collapsible containers do not exist for effecting the proper mixing of ingredients at the time sufficient pressure is applied to the collapsible container.

5 Present needle-less jet injector systems are very expensive. For one thing, these systems draw the serum or other injecting fluid into disposable capsules having walls thick enough to withstand the high pressures of about 1,700 psi or more for human IM injections.

Another problem with jet injector systems is that they "gum up" from the  
10 injectant material if the user fails to thoroughly clean the device on a timely basis. In some situations, such as field use with cattle, this procedure is difficult, if not impossible, in terms of available time and equipment.

Some injection fluids have higher viscosities than water, such as the BST growth hormone, Posilac, for enhancing milk production. If the fluid becomes too  
15 viscous because of lower temperatures, proper injection would not be possible. Presently, no temperature measuring systems for injection fluids are available.

#### Summary of the Invention

It is an object of the present invention to provide an improved injection system for injecting materials such as vaccines, sera, growth hormones, vitamins, nutrients, and  
20 the like into a living body.

It is another object of the invention to provide a system for injecting material of the foregoing type into a body to obtain an effective injection even though the body may move somewhat during the injection process.

Yet another object of the invention is to provide a system for effectively  
25 injecting materials of the foregoing type through thick outer layers of a body and evenly disbursing the fluid from a high velocity, piercing jet stream at the inner regions in the event this is the desired target area.

It is a more particular object of the present invention to provide an injection system for injecting material of the foregoing type into large animals, such as cattle,  
30 having thick hides.

Another object is to provide an improved collapsible container or containers for holding material to be injected into an animal or person, once sufficient pressure is

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applied to the collapsible container or containers.

Yet another object is to provide an improved collapsible container or containers for holding injectant material which can bring together different ingredients to be injected once sufficient pressure is applied to the collapsible container or containers.

5 It is still another object to provide a jet injection system for injecting the foregoing types of materials into animal and human bodies having low-cost capsules with thin-walled cavities for holding the material to be injected.

Another object is to provide an effective injection system having multiple orifices for effectively reducing the time required for injecting a larger dose of material  
10 into animals and humans or for injecting multiple products at the same time.

Another object is to provide means to deposit each of the multiple products at different locations and/or at different injection depths.

it is still another object to provide means to inhibit injection site pain for the injection of singular or multiple products.

15 Another object is to provide electrical stimulation to dull injection site pain.

A further object is the provision of an injection system for preventing actuation of the system until certain conditions are met.

Another related object is to provide an injection system having a trigger which is actuable only when an anti-splash guard ring is properly in contact with the surface  
20 through which the injection is to be made.

Another object of the invention is to automatically provide an injection site mark or legend as an indicator that a group of animals or humans have already received a particular injection.

It is an additional object to prevent the unauthorized use of an injection  
25 apparatus.

Another more particular object is to provide an injection system having a trigger which is actuable only when an access code is first keyed into the system.

It is yet another object of the invention to provide a jet injection system having a hybrid needle/orifice combination which is designed to proceed through the outer  
30 layer of a body and obtain a more effective dispersion of the injectant material at a preferred injection site.

A further object is the provision of a hybrid/orifice combination jet injection

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system for animals which is so constructed that the system will not be impaired even if the animal moves during the injection process.

It is also an object of the present invention to provide an injection system having batteries or a storage capacitor which can be recharged with solar energy.

5 Another object of the invention is to provide a solar powered jet injection system and a solar generator for powering the jet injector at remote locations away from access to central electric power supplies.

Another object is to provide a light weight, easy to handle, injection system to allow for injections at a significant distance from an animal when close proximity is  
10 difficult to realize.

It is still another object of the present invention to provide a robotic injection system for the automatic injection of subjects such as the living bodies of humans and animals.

An additional object of the present invention is to provide an injection system  
15 with a replaceable component for connecting the system to a reservoir.

A further and related object is the provision of an injection system with a replaceable component for connection to an injection chamber and integral orifice.

Another object is to provide an injection system for mixing lyophilized ingredients at the time of an injection.

20 It is yet another object of the present invention to provide an injection system having a replaceable exit channel, orifice device, and/or a replaceable needle device, used in connection with a permanent medication chamber.

It is still a further object of the present invention to provide a temperature monitor for measuring the temperature of materials to be injected.

25 Another related object is the provision of a temperature monitoring device for an injection system for disabling the injection system if the temperature drops below threshold value(s).

A general object of the present invention is to provide an efficient, effective, yet economical system for injecting animals and people.

30 Other objects will become apparent from the description to follow and from the appended claims.

One form of the present invention makes possible the quick completion of the



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injection process through the hide of an animal. This form comprises a short perforating member with a jet system for forcing an injecting fluid under high pressure through the perforating member. Depending on the location of the injection, the perforating member of this hybrid combination is from 1/8 to 3/8 inch or more in length and is surgically sharp with a slanted point for easy insertion. When the perforating member is pressed into the hide of an animal, it creates an anchor point therefore eliminating the detrimental risk of movement by either the person making the injection or by the animal. The high pressure, high velocity jet stream from this vantage point is not deflected by the hair on the hide or the tough outer layer so that the jet flow remains coherent. The sharp, slanted needle point moves the debris aside rather than forcing it into the hide. Since the perforating portion of the hybrid combination extends through the hide, less injection pressure is necessary to reach the subcutaneous layer or into the muscular region of the animal if this is the injection site of choice. Consequently, lower motor torque is required, thereby allowing for a smaller power source for an equal number of shots than required by prior art systems. In addition, the orifice portion of the hybrid combination can be increased in size to provide for a faster discharge of the injection material thus allowing for larger doses with the same injection time. The lower cost motor and power source, along with a smaller and lighter weight for the system render it more economical and easier to use.

Because of the low cost, the hybrid perforator/orifice combination can be discarded after each use, further eliminating cross-contamination. Another embodiment of the invention incorporates a protective containment chamber into which the hybrid perforator can be withdrawn after the injection is completed, making the needle portion inaccessible for subsequent reuse, providing yet another way for preventing cross-contamination. When a jet injection is given through the perforating member, the orifice portion of the combination generates a coherent, evenly dispersed jet stream without having the needle portion penetrate the muscle, and thereby avoid the large economic loss in the meat industry from prior art needle injections.

Another aspect of the present invention is the provision of a collapsible container for holding one or more materials to be injected, having a needle device for injecting the material once collapsing pressure is applied to the container to force the materials from the container.

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A further version of the invention is the provision of a collapsible container for a hypodermic system having holding containers or reservoirs (hereinafter generally referred to as "reservoirs") for ingredients to be combined for injection, and a needle device for penetrating a reservoir when sufficient pressure is applied to the collapsible container to cause the ingredients to be combined.

Another form of the present invention enables the use of low-cost, thin-walled capsules for holding the materials to be injected, even though the capsules must be able to withstand pressures commonly used with jet injection procedures. According to this version of the invention, the thin-walled capsule is held in a restraining structure, similar to a gun barrel, which serves to protect the capsule from expanding, bursting, or even leaking, as a result of the high pressure. The use of a restraining structure with a thin-walled capsule enables the mass immunization of animals and humans at a cost no greater than that experienced with conventional needle/syringe systems, but without all of the risks associated with needles. A restraining structure and thin-walled capsule eliminates the requirement for conventional needle injections and also eliminates the high cost of the thick-walled capsule of prior art systems. The hybrid perforator/orifice concept can also be used with the restraining structure and thin-walled capsule for higher pressure injections into thick skinned animals, thus realizing an economical approach for this application as well.

Another aspect of the present invention is a jet injector system with multiple orifices for enabling fast injections of high doses of injecting material than heretofore possible. The number of orifices generally equals the number of times faster that an injection can be made. Multiple orifices could be used in human surgery, such as for plastic surgery where a fairly large surface pattern must be anesthetized, or in combination with multiple capsules to administer more than one serum product simultaneously at adjacent points of entry and, if advantageous, to further discourage the mixing of products at the injection site by providing for different injection depths for each product at each point of entry.

To better suppress the possibility of pain, another aspect of the invention provides for electrical stimulation to desensitize the injection site. This technique is especially useful with the added risk of pain due to multiple, simultaneous points of entry with either high velocity jet streams or needles.

Still another version of the present invention disables the actuation of the inventive system until additional predetermined conditions are met. An embodiment of this version includes a second switch in series with the actuating member such as a trigger.

5 In order to eliminate the battery disposal problem which could accompany battery-powered jet injection systems at remote locations, another embodiment of the present invention utilizes methods of energizing the low power requirements of an electrical injector. One version of this embodiment incorporates a relatively small gel cell or fluid electrolyte battery connected to a single injector or multiple injectors with  
10 light weight, low cost extension wires. For example, multiple injectors could be operated at the same time at remote health centers dealing with epidemic immunization requirements. The power sources for the injectors would be rechargeable directly from the transport vehicles if available. Such recharging can also come from an inexpensive low-power solar charger or directly driven with a solar generator of greater capacity.  
15 These recharging systems pursuant to the invention can eliminate the need for grid power or the more expensive and generally unwieldy electrical generators, carbon dioxide tanks, hydraulics and breakable foot pedals.

Another version of the invention is a robotic system. Herds of cattle ordinarily pass through separating chutes when they enter the barn. Animals to be injected can  
20 be electronically identified and separated from the herd. Such an identification could be by means of tags with bar codes. The separated animals could be restrained, and a long arm of a robotically-operated jet injector would inject the restrained animals and then release them when completed, pursuant to this version of the invention.

In a related version to the long arm of the robotic system, a long-armed manual  
25 system is provided with the injection mechanism and a surface contact enabling head at the target end and an actuating trigger at the user end. This embodiment has utility for the injection of large animals such as pigs, since getting close to the animal is sometimes difficult and/or inconvenient. Such a system could allow for removal of the robotic arm and use in the manual mode. The extended arm concept can be provided  
30 as a totally independent manual system.

Another aspect of the present invention comprises an automatic marking system. The automatic marking system is used with respect to large numbers of animals or

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humans in close proximity to each other. The system includes a nozzle adjacent to the injection nozzle. The marking system automatically marks the subject when an injection is given. The marker, which should be a non-toxic dye, is preferably such that its expected life does not exceed the time between injections. Different indicia, such as using more than one color of the dye, will make multiple injections distinguishable. In this way, the user is able to tell which of the animals and/or humans in a large, close proximity group have already been injected with a particular product so that none are missed and none are injected more than once.

Another version of the present invention involves the elimination of the "gumming-up" which frequently affects jet injectors if the user fails to clean the device on a timely basis. According to this version of the invention, the jet injector gun has, as an integral unit for each serum to be administered, a tube for connection to the reservoir having the injectant material, a chamber and an orifice, which is inserted into the gun as a single composite system containing all of the elements necessary for delivering one or more serums at the same time. During a series of shots, the injectant fluid or fluids are drawn into the chamber or chambers and injections are given through the integrated orifice system. At the completion of the entire series of shots, the integral unit is removed and discarded. Only the removable and disposable integral unit contacts any injection fluid; the gun itself does not contact any fluid and does not gum-up. The system could be used with a single-shot disposable orifice and perforator for each fluid to eliminate cross-contamination.

#### Brief Description of the Drawings

The invention is illustrated in the accompanying drawing in which:

Figs. 1 and 4 illustrate side, cross-sectional views of two multiple inoculation jet injectors in accordance with the invention;

Fig. 7 is a partial pictorial view of a modified body ring guard for use in the injectors of Figs. 1 and 4;

Fig. 8 is a pictorial view of a modified nozzle for use in the injectors of Figs. 4 and 7;

Figs. 2 and 5 illustrate cross-sectional views of jet injector systems with the fresh injectors of Figs. 1 and 4, respectively, installed therein;

Figs. 3 and 6 illustrate side, cross-sectional views of the jet injector systems of

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Figs. 2 and 5, respectively, with the injectors partially expended;

Fig. 9 is a schematic diagram illustrating a fly-wheel system as an alternative to the spring of Fig. 2, 5, 3 and 6 for producing injection pressure;

Fig. 10 shows a cross-section of a mechanical latch when the flyweights of Fig. 9 are in the most inward position;

Fig. 11 shows the latch of Fig. 10 in final release, when the flyweights are in the most outward position;

Fig. 12 shows a rotating hydraulic latch in the locked position;

Fig. 13 is a schematic diagram of apparatus for the direct drive of the forces for an injection procedure.

Fig. 14A, 14B and Fig. 18 are schematic representations of one embodiment of the control, monitoring, and motor drive circuitry of the jet injector system of Figs. 2 or 25;

Figs. 15 and 16 are schematic representations of alternative embodiments for the motor drive circuitry in the jet injector system of Figs. 2 and 25;

Fig. 17 is an alternate embodiment of the power switch shown in Figs. 14A, 14B;

Figs. 19 through 23 illustrate side, cross-sectional views of a needle hypodermic injector in accordance with another embodiment of the invention;

Fig. 24 is a block diagram overview of a multiple inoculation jet injector system in accordance with another embodiment of the invention;

Fig. 25 is a pictorial view of another embodiment of a jet injector in accordance with my invention;

Fig. 26 shows an oversized perspective view of the injector shown in Fig. 25, with a fresh magazine with N unused injections positioned in the dispenser;

Fig. 27 shows the oversized magazine illustrated in Fig. 26 with the injections having been used;

Fig. 28 is a pictorial view of the jet injector wherein the rechargeable power source is a removable module and a multi-dose container is connected to the injection head to permit the rapid continuation of an injection procedure for a large number of subjects;

Fig. 29 is a pictorial view of the embodiment shown in Fig. 28 in use;

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Fig. 30 shows the format of another embodiment of the invention showing an injector capable of being driven by alternate sources of electrical power;

Fig. 31 is an exploded pictorial view of a jet injector system according to another embodiment of the invention, using thin-walled capsules in a high pressure injection chamber;

Fig. 32 is a pictorial view of a disposable, anti-gumming sub-system according to another embodiment of the invention, having a replaceable serum container, connecting hose, injection chamber and exit orifice as a single unit;

Fig. 33 is a pictorial, partial view showing a multitude of exit orifices from a single injection chamber;

Fig. 34 is a pictorial illustration of another embodiment of the invention showing multiple independent injection chambers each having its own exit orifice;

Fig. 35 is a detailed, pictorial view of a single injection chamber and exit orifice from the multiple chambered system of Fig. 34;

Fig. 36 is a pictorial view of a cow receiving a jet injection with a robotic arm according to another embodiment of the invention;

Fig. 37 shows a side, partial view of the jet injector system illustrated in Fig. 25 with a fresh cartridge installed therein;

Fig. 38 shows a side, partial view of the jet injector system of Fig. 25 in which the cartridge has been breached;

Fig. 39 is a schematic showing the "pooling" effect when the injectant is introduced into the injection site using the prior art needle and syringe occurring after an injection;

Fig. 40 is a schematic illustrating an encapsulated perforator prior to insertion, according to another embodiment of the invention;

Fig. 41 is a side view of a perforator with a slanted tip according to an embodiment of the invention;

Fig. 42 shows in schematic the perforator of Fig. 40 inserted in the hide of an animal with a protective shield fully compressed;

Fig. 43 shows in schematic form an injection system with jet stream degradation when the entrance point for the jet stream is the outer surface of the hide, under a prior art system;

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Fig. 44 is a schematic view of a perforator with a conventional jet orifice located at the input channel of the perforator;

Fig. 45 is a schematic view of an embodiment of the invention showing a permanent jet orifice with a removable perforator;

5 Fig. 46 shows schematically the jet orifice located at the exit end of the perforator pursuant to another embodiment of the invention; and

Fig. 47 shows a schematic view of a very short, flat, non-sharpened tubular orifice serving to stretch and detent the injection site in preparation for the high velocity jet stream according to a further embodiment of the invention.

10 Detailed Description of the Embodiment

Fig. 1 illustrates a liquid filled jet injector or dispenser 1 stored in a protective cover 110. The jet injector of Fig. 1 comprises a liquid-filled bellows 100; a front plate 102 which comprises a pair of guide rod recesses 111 and 112, a set of thin washers 116 which have an inner diameter slightly larger than the minor diameter of bellows 100, a pair of holes 117 in each of the washers 116 that are aligned with the 15 guide rod recesses 111 and 112 and with the openings 105 and 106; a spacing guard ring 103, with an interrupted pattern 901 shown in Fig. 7 to prevent sliding between the dispenser and the skin; a disposable and replaceable exit nozzle 101 with an output port 109 (shown in greater detail in Fig. 8); a ram 113 with a groove 114; and a back plate 104. Guard ring 103 can advantageously have the features shown in Figs. 7 and 20 8, respectively. An interrupted pattern 901 at the end of ring 103 in Fig. 7 prevents sliding between the dispenser and the skin of the person being injected. The nozzle 101 has its end 903 threaded in Fig. 8 or the like so that it can be disposable and replaced. The back plate 104 comprises openings 105 and 106, aligned with holes 117 in washers 116, which accept a pair of guide rods when the jet injector cartridge is 25 installed in the system of Figs. 2 and 3; and a ring 115 which forms the recess 107 for receiving a drive spring 227 of the system of Fig. 2. The injector of Fig. 1 may be a disposable injector or a multitude of permanent reusable injectors for the administration of, for example, the growth hormone. The attendant can pre-fill a multitude of the cartridges shown in Fig. 4 carrying them in a belt holster, or as shown 30 in Figs. 28 and 30, in a single large container or sack with a hose connected to the injection chamber. The output port can be made of ceramic, plastic, glass or metal and

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may be removable and replaceable or a permanent part of the injection head. In either case, device economy is improved by fabricating a molded output port having the flow orifice formed by first inserting a preformed metal, or other sufficiently sturdy member, whose size and shape, i.e., length, diameter and flow path angulation are  
5 chosen to provide laminar flow. Some of the other possible methods for forming the orifice include laser boring, water jet cutting and electron beam cutting.

Fig. 2 is a cross-sectional representation of an illustrative embodiment of a hypodermic jet injector system with a fresh jet injector of Fig. 1 installed therein. The system of Figs. 2, 3, 5, and 6 in general comprises: a housing 220; the control,  
10 monitoring and display arrangements of Figs. 14A, 14B and 18 (not shown in Fig. 2); an electric drive motor 221; a motor output shaft 222 with a threaded portion 223; a loading ram 224 with internal threads 225 which mate with the threads 223; an energy storage spring 227; a reluctance transducer shield 226 to be described with respect to Figs. 14A, 14B later herein; a pair of guide rods 228 and 229 that serve to align and  
15 support the bellows 100; retaining latches 238 and 239; and a trigger mechanism which comprises the detents 232 and 233, the follower springs 230 and 231 and the follower blocks 234 and 235. The mechanism for releasing the detents 232 and 233 is not shown in Fig. 2 and any suitable mechanical linkage which effects the simultaneous lifting of the detents 232 and 233 is satisfactory. In an alternative mechanical  
20 embodiment for loading energy storage spring 227, threaded motor shaft 222 is replaced with a shaft driven cam which serves to compress energy storage spring 227 as the motor shaft rotates.

An alternate embodiment of the injector of Figs. 1, 2 and 3 is illustrated in Figs. 4, 5, and 6. In the alternate embodiment, the liquid-filled bellows 100 is replaced  
25 by a collapsible liquid-filled "hat" diaphragm-type structure. Detents 111 and 112 of Fig. 1 are replaced in Fig. 4 by slot 120 for mounting and firmly securing hat structure 122 to the front plate 102. This arrangement is equally effective if the fluid chamber is replaced by a piston-type syringe.

Fig. 5 is a cross-sectional representation of the injector system with a fresh  
30 injector installed therein. When the diaphragm 122 is inserted in the now conformal housing 220, a slight initial collapse of 122 occurs to facilitate chamber venting and to assure an effective inner folding action as the multiple injections follow. The



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conformal shape of housing 220 constrains fluid chamber 122 and thus prevents undesired outward expansion under the influence of the injection pressure when the spring 227 is released. Back plate 124 is configured to assure that the detents 232 and 233 do not interfere with fluid chamber 122 as it progressively folds inside its outside diameter (Fig. 6) with each additional injection. In the case of the syringe, the piston is progressively pushed to the right as the injections occur.

While the following discussion is specific to the embodiment of Figs. 1, 2 and 3, the discussion applies equally to the alternate embodiment of Figs. 4, 5 and 6 and the piston-type syringe dispenser.

10 Prior to the time that a fresh jet injector of Fig. 1 is installed in the system of Fig. 2, a manually operable reset switch 436 of Fig. 18 is operated to enable the IC Set circuit 426 of Fig. 18 to establish initial system conditions. The output signal of the circuit 426 enables motor control functions 351 of Figs. 14A, 14B to draw the loading ram 224 back into the initial position illustrated in Fig. 2 or to rotate the cam to its starting position; output signal 427 initializes the digital pulse decoder 324; output  
15 signal 428 is transmitted to the digital window decoder 386; and signal 429 is transmitted to the pulse decoder, counter, and display 424. Alternatively, the ram 224 or the cam can be manually returned to the initial position at the time that a fresh bellows is installed.

20 The functions of the pulse decoder 324, the window decoder 386 and the pulse decoder counter and display 424 will be apparent from the description of Figs. 14A, 14B and 18 which appears later herein. After the system is thus conditioned, a fresh jet injector is removed from the protective cover 110 and inserted into the housing 220 as illustrated in Fig. 2. To install the jet injector, the guide rods 228 and 229 are  
25 inserted into the openings 105 and 106 in the back plate 104, through the openings 117 in the washers 116, and the injector is moved into the housing 220 until the front face of the front plate 102 is clamped by the latches 238 and 239. As the jet injector is moved into the housing 220, the detents 232 and 233 engage the notches 108 in the back plate 104 and follow the motion of the back plate as it is moved to the left in  
30 Fig. 2. The follower blocks 234 and 235 follow the motion of the detents 232 and 233 to the left and thus compress the follower coil springs 230 and 231. Further, when a fresh injector is in position as illustrated in Fig. 2, the energy storage spring 227 enters

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the recess 107 in the back side of the back plate 104. The system of Fig. 2 is in condition for an operator to perform a series of inoculations.

Under operator control, the system of Figs. 2, 14A, 14B and 18 selectively provides power to the motor 221 to advance the ram 224 to the right in Fig. 2 and thus compress the coil spring 227. As described later herein, the circuitry of Figs. 14A, 14B monitors the degree of compression of the spring 227 and removes power from the motor when the compression reaches a target value or when the selected flywheel speed of Fig. 9 is reached. The target value is either a default value established by the manufacturer or a value established by an operator on the basis of experience. After the spring has been compressed or motor speed reaches the target value, the guard 103 is held perpendicular to and against the skin at a suitable site of a subject to be injected. The outer ring surface of guard 103 may have a tooth-like pattern 901 to reduce the possibility of the ring sliding along the skin during the course of an injection. Guard ring 103 can also contain electrical pain suppression contacts. If the ring does slide during the injection the subject may receive a "jet cut" rather than a jet inoculation. The operator initiates injection by depressing a trigger, which as indicated earlier herein is not shown in the drawing. Depression of the trigger simultaneously releases the detents 232 and 233 from the recesses 108 in the back plate 104. The energy stored in the spring 227 is released and the back plate 104 is rapidly driven to partially collapse the bellows 100. As the bellows is collapsed, a desired amount of fluid is driven through the output port 109 in the projection 101. Advantageously, the use of a compressed spring as a source of energy provides a high initial pressure which reduces as the bellows 100 collapses. The size and the length of the port 109 and the pressure profile supplied by the compressed spring projects the fluid with a desired pressure profile which assures hypodermic injection of the fluid to the desired depth. The diameter and the length of the port 109 are chosen to assure laminar flow of the fluid from the chamber to the output tip. As the bellows collapse, guide washers 116 move together and prevent the bellows from bending under the influence of the high initial force of the injection.

As explained earlier herein, when a fresh injector is inserted into the housing 220, the follower springs 230 and 231 are compressed. Therefore, after the trigger is released, the follower blocks 234 and 235 and the detents 232 and 233 are driven to

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the right in Fig. 2 until the detents again engage the corresponding recesses 108 in the back plate 104. The follower blocks 234 and 235 may be connected to a small dashpot if a delay in this action is desired. The system of Fig. 2 is then again ready for the operator to initiate another injection.

5           Because the wall of the bellows 100 has a finite thickness, a fully collapsed bellows has a substantial length. The length of the ram 113 approximates the length of the collapsed bellows. Without the ram 113, valuable fluid is left in a fully collapsed bellows. The groove 114 in the ram 113 prevents the trapping of fluid in the portions of the bellows which surround the ram 113.

10           Two additional alternatives to spring 227 can provide the pressure needed to give an effective injection. The first is a motor-generator in combination with an energy storage flywheel as shown in Fig. 9. This embodiment represents a device for another method of intermediate energy storage when the power source is insufficient for a direct drive injection, and is especially useful for realizing a compact, lightweight  
15           design, even when a much higher pressure is required for an effective injection. In the second embodiment shown in Fig. 10, injection pressure is developed directly from the motor with no intermediate storage of energy, such as a spring, compression chamber or flywheel. However, if applicable, an energy storage flywheel could be advantageously used with the drive mechanism shown.

20           The components of one version of a flywheel system of Fig. 9 are the housing 1A for the flywheel with rear extension 2 and front extension 3 to enclose the other moving parts. A motor 4 capable of accelerating to high speeds directly drives a spindle 5 rotating in a rear bearing 6 and a front bearing 7. At least two flyweights 8 swing on arms 9 on a set of pivot bearings 10 fastened to spindle 5. Arms 11 are  
25           rigidly attached to arms 9 and the flyweights 8. The centrifugal load of flyweights 8 is transmitted from arms 11 to a pair of links 12 through a pair of pivot bearings 13, then through a pair of pivot bearings 14 to a thrust rod 15. Rod 15 rotates with the spindle 5, and moves axially to the left in Fig. 9 as the radial distance of the flyweights from the central axis increases. The thrust load is transmitted to a plunger  
30           or ram 16 which moves axially without rotating and provides the force required for operating an injection device. Thrust bearing 17 is therefore required for transmitting the load from rod 15 to plunger 16. Plunger 16 transmits a pressure or load to a

container C to effect the discharge of an injectant as a jet stream.

The reaction from thrust bearing 17 is exerted at bearing 6, which must have a thrust capability equal to that of thrust bearing 17. Ball or roller bearings, which can be used for these bearings, should have very low friction, but the energy loss can be substantial because of the high loads and speeds. A rotating latching device 18 which locks all of the rotating parts together can eliminate the thrust load losses during acceleration. The latch could operate directly on the flyweights or could latch thrust rod 15 to the spindle, as indicated in Fig. 10.

A constant-inertia wheel or flywheel 19 can be added for storing additional energy during acceleration that would compensate for thrust bearing and other losses during the injection phase, after latch release.

A light spring 20 restores the mechanism to the initial position after injection. It may be desirable to apply electrical or mechanical braking to stop flywheel rotation after injection. The energy loss from braking will be small since the speed is already greatly reduced.

The magnitude and variation of inertia, the characteristics of the flyweight-thrust rod linkage mechanism and the friction losses affect the force variations during injection. The linkage shown has an increasing mechanical advantage as the flyweights move outwardly, partially offsetting the decrease in centrifugal force from the speed drop caused by the increase in the moment of inertia and by the friction losses.

Figs. 10, 11 and 12 show rotating latch designs. However, many parts required for assembly are not shown as individual items for reasons of clarity. While these figures are directed to a particular design concept, it should be noted that numerous methods of mechanical, hydraulic, magnetic and electrical latching systems are applicable. For example, release of the hydraulic latch of Fig. 12 can be facilitated with a variable force spring, wherein, as the motor accelerates to reach the selected speed, centrifugal force will increase accordingly. When centrifugal force finally exceeds the holding force of the variable tension spring, the latch will release. In another centrifugal force embodiment, the spring is replaced by holding magnets or, as an alternative, the flyweights themselves are magnetically held. In this case, break-away will occur when centrifugal force exceeds the holding force of the magnets. A variable holding force with the magnets can be achieved by changing the amount of

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overlap between the magnet face and the metal plate to which it is attached.

One embodiment of an electrical release that is applicable to Figs. 10 and 11 utilizes a motor tachometer. In this case, the user will dial or key into the system the desired injection pressure, that is, motor RPM. When the target speed is achieved, an electrical signal is emitted to actuate a solenoid. Alternatively, a coil wound around one or more holding magnets could be energized to momentarily reduce the holding force and a release will occur. Using an RPM dependent signal will assure a consistent release point and will avoid the possibility of release error due to variations that may occur in the non-electrical holding means described above.

10 Turning now to a detailed explanation of Figs. 10, 11 and 12, Fig. 10 shows a mechanical latch in the position which locks thrust rod 15 to spindle 5, when the flyweights are in the most inward position. Fig. 11 shows the same latch in the final released position, when the flyweights are in the most outward position.

Two diametrically opposite pairs of rollers 21 roll on a flange 22 on spindle 5 and on two diametrically opposite lugs 23 on thrust rod 15. A pair of axles 24 fastened to a pair of cylinders 25 and 26 hold the rollers in axial alignment. These cylinders 25, 26 can turn freely on flange 22 and rod 15 but are held in axial alignment with each other by a set of keys 27. The keys allow slight axial movement between cylinders 25, 26; therefore, the thrust load is transmitted through rollers 21 without putting any significant load on the axles.

20 Release is triggered by moving a pair of prys, wedges or inclined planes 28 axially to the right, forcing rollers 21 in cylinder 26 to roll off lugs 23. The thrust load is then transmitted to plunger 16 (Fig. 9) and rod 15 moves axially to the left. Wedges 28 project from a ring 29 through slots in flange 22. Ring 29 slides freely on spindle 5, but is forced to rotate with the spindle by the wedges 28 in the slots. The trigger moves a non-rotating collar 30 and the wedges axially.

One end of latch 18 is supported when rod 15 slides in a rotating member, which in this case is a hollow drive shaft 31, which turns rod 15 with keys or splines 42. Shaft 31 is supported by a bearing 32.

30 The direction of flywheel rotation would preferably be in the same direction in which cylinders 25 and 26 must rotate for release (i.e., clockwise in Figs. 10 and 11 when viewed rightward from the left ends). Relatching can then be accomplished by

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momentarily retarding a cylinder with a brake 43 when starting, while the force from spring 20 exceeds the flywheel thrust and holds rod 15 against the right limit of its travel.

5 A trigger 70 comprises a yoke 44 which is pivoted on a pair of pins 45 in housing 2 and which contacts a pair of pins 46 on collar 30. A bias spring 47 attached to trigger 70 and housing 2 maintains the locked position until release is triggered manually or by an electrical solenoid 48, also attached to the trigger and to the housing.

10 Fig. 11 shows rollers 21 as if they revolved 90 degrees from their position in Fig. 10, but the angle can be any value within a range set by the clearance between rollers 21 and lugs 23 and wedges 28.

Features of this latch are that there are no highly-loaded bearings and no radially outward mass transfers, which would reduce speed without producing any useful thrust.

15 The need for a hollow keyed drive shaft 31 can be eliminated by a latch designed to operate at the left side of Fig. 9 or by interchanging the positions of the motor and the injection device. The injection device must be designed for a pull, rather than a push, from the thrust rod in the latter case.

20 Fig. 12 shows a rotating hydraulic latch 18' in the locked position. A cylinder 33 at the end of spindle 5 is filled with hydraulic fluid F. An inner cylinder 34 contains fluid F which is at an elevated pressure in the locked position. Cylinder 34 has end walls with openings 35 through which fluid can flow freely. The pressure is produced by a piston 36 and rod 15, which transmits the thrust load to fluid F. Seals 37 and a seat 38 prevents leakage. Part numbers correspond to those in Figs. 10 and 25 11 where corresponding parts are employed.

30 Inner cylinder 34 is moved a small distance to the right by collar 30 to form an opening at seat 38 and release the pressure on the left side of piston 36. The fluid flows between cylinders 33 and 34, and flows into the increasing volume to the right of piston 36 as the piston moves to the left. The fluid volume within the latch remains constant. No flow to or from the outside is required. A pair of seals 39 complete the sealing of latch 18' and are not exposed to high pressures. A projection 40 from inner cylinder 34, with a vent 41 to the atmosphere, permits a constant volume system and

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balancing of the trigger load.

The diameters of piston 36 and seat 38 can be proportioned to produce a particular trigger force at a particular speed in either direction. If the force on collar 30, originating with flyweights 8, is to the right in Fig. 12, latch 18' will trip automatically at a load set by bias spring 47, a screw 49, and an adjusting knob 50 in the housing. Another feature of latch 18' is that it can easily be locked at any position of the flyweights and plunger 16 (Fig. 9) before acceleration begins. This facilitates injection of varying serum volumes from one size cylinder or capsule.

Fluid pressures in the latch can be much more moderate than the injection pressures if the latch diameters are sufficiently large.

In the direct drive system of Fig. 13, a high torque gearmotor 52 rotates a cam 53 (clockwise in Fig. 13) whose increasing radius directly drives a cam follower 54 which in turn transmits a drive force to compress a piston 56 in injection chamber 57 to expel the injectant through an exit port 58. A force transducer 59 continuously detects the force exerted on piston 56 and generates a feedback signal 60 that increases or decreases drive power to the motor drive through a controller 61 powered by a battery B, in order to maintain the target pressure throughout the injection cycle. A return spring 62 pulls piston 56 back to its starting position when cam 53 rotates beyond the maximum stroke of the injection cycle. An optional motor-generator and constant inertia flywheel (not shown) is also applicable for energy storage if insufficient short term power is available for a direct drive system.

The cam follower 54 and piston 56 in Fig. 13 could be replaced by other means for transmitting a drive force, and piston 56 and injection chamber 57 could have other forms rather than the piston and cylinder as shown. Piston 56 could be other ram means and the injection chamber could be other containers from which the injectant is expelled.

The above description is a general outline of the inoculation process with detailed reference to the means for developing injection pressure, system control, monitoring, motor drive and display apparatus of Figs. 14A, 14B and 18. While it is our intent to provide safe, low cost and convenient-to-use hypodermic injectors, we also provide measures of electronic monitoring, motor drive and control not found in known jet injectors.

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Fig. 24 provides a block diagram functional overview of a hypodermic jet injector system in accordance with my invention. The dotted line of Fig. 24 provides a logical division between the mechanical portions of the injector system and the electronic monitoring, motor drive and control portions of the system.

5        The functional boxes 1001 through 1006 of Fig. 24 correspond to elements of the illustrative embodiment of Figs. 2 and 3 as follows:

	<u>Fig. 6</u>	<u>Fig. 2 or 9</u>
10	Energy Source 1001	Motor 221
	Mechanical Energy Storage 1002	Spring 227 or flywheel 8
	Pressure Restraint 1003	Detents 232 and 233 or latch 18
15	Trigger Release 1004	Not shown in drawing
	Serum Chamber 1005	Jet injector of Fig. 1 including Bellows 100
20	Exit port and contact enable 1006 and electrical pain suppression 1006'	Output port 109 and guard ring 103

Although the illustrative embodiment of Fig. 2 employs an electrically-operated  
 25    geared down motor 221 to compress the coil spring 227, this requirement can be fulfilled by a variety of manual arrangements utilizing gears or other means of mechanical advantage. While the spring is preferred for storing mechanical energy, the blocks 1001 and 1002 of Fig. 24 could be replaced by other arrangements, e.g., a powerful solenoid, gas, hydraulic pressure, the flywheel, or direct drive cam discussed  
 30    earlier. The critical requirement of the blocks 1001 and 1002 is that the serum chamber 100 receives enough force for a sufficient period of time to assure an effective inoculation.

The monitoring functions of Fig. 24 inform an operator when the device is ready to perform an injection, i.e., all system parameters are within acceptable limits  
 35    of performance. A warning is issued when performance is not within limits and the system is disabled in the event of a malfunction.

The pressure sensor 1007 of Fig. 24 monitors the status of the energy storage



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device 1002 and compares the magnitude of the stored energy to a target magnitude. When the magnitude of the energy stored reaches the target value, the storage of energy is terminated. The target value may be a default value established by the manufacturer or a value established by the operator on the basis of experience with different subjects, e.g., adults, children, animals, and/or types of serum. DNA technology, agricultural procedures and different types of serum may be better served with different pressures. The target pressure value is one of the "initial conditions" which an operator may set by controls in the IC Set function 1010 of Fig. 24.

The volume sensor 1008 provides assurance that a correct amount of liquid is used in each injection.

The velocity sensor 1009 of Fig. 24 determines the time required for the stored energy to decay to some predetermined value after an injection. The decay time is a measure of output port performance. If the output port is partially clogged, the pressure decays too slowly; and if the output port is worn or too large, the pressure decays too rapidly. If a failure is detected, a warning will be issued to the operator and the system is disabled until corrective action is taken.

The IC Set 1010 of Fig. 24 permits an operator to select initial condition values for the pressure sensor 1007, the volume sensor 1008 and the velocity sensor 1009.

The processor and decision logic 1011 issues control signals to the system power control 1013 and status signals to the monitor display and warning unit 1012.

In addition to the control and monitoring function described above herein, the circuit arrangements of Fig. 18 maintain a record of the number of injections completed or, in the case of the cartridge system described below in relation of Figs. 26 and 27, the number of cartridges remaining as the cartridges in the magazine are used up.

The implementation of the system functions by the arrangements of Figs. 14A, 14B and 18 will be understood from the following description.

Digital inverters 310 and 312, resistors 314 and 316, and capacitor 318 are configured to form a reference frequency oscillator. The operating frequency  $F_n$  is determined by the time constant of the resistor 314 and the capacitor 318. This oscillator, or a separate oscillator, can provide the pain suppression signal for electrical pain suppression function 319 and surface contact pads or guard ring 321.

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Digital inverters 300 and 302, capacitor 308, and variable sensing inductance 304 in Figs. 14A, 14B form a variable frequency reluctance transducer oscillator which has an operating frequency  $F_p$ . The operating frequency of the oscillator varies as a function of the value of the inductance in coil 304. The coil 304, which is not shown in Fig. 2, is mounted at the center of recess 107 and inside the energy storage spring 227 and is partially covered by the reluctance shield 226 of Fig. 2. It is noted that reluctance shield 226 is shown to the outside of spring 227 for illustrative clarity, however, it is ideally situated at the inside diameter of spring 227, which is quite large in order to develop 1700 psi or more as needed for an effective deep penetration injection for human use or 6000 psi or more and for sufficient penetration of a dairy cow. In any event, a change in the relative position of the coil 304 and the shield 226 as the spring 227 is compressed changes the inductance of the coil 304. Accordingly the frequency of the oscillator, which is determined by the time constant of the inductance of coil 304 and the capacitor 308, is determined by the degree of compression of the spring 227. A reluctance transducer oscillator with a sensing inductance as described above is known from my U.S. patent application 07/625,942, filed December 11, 1990, for "Inductance Systems." It is noted that other types of oscillator networks can also be used for these functions, for example, analog comparators or amplifiers.

Flip flop 320 is configured as a frequency mixer which provides a digital output signal which has a pulse rate  $F_{dl}$  which is the difference between the reference pulse rate  $F_{rl}$  and the oscillator frequency  $F_p$ . In the absence of pressure on the spring 227, the frequencies  $F_{rl}$  and  $F_p$  are equal and the pulse rate  $F_{dl}$  at the "1" output of flip flop 320 is zero.

In the illustrative embodiment of Figs. 14A, 14B, energy enhancement techniques drive motor 221 with a series of high speed, high energy and relatively high voltage pulses. The output of AND gate 338 controls the generation of the motor drive pulses. The inputs to the AND gate 338 comprise: the "0" output of the flip flop 336 which remains high until the target value of spring compression is reached; the BT conductor from pulse decoder 424; the "0" output of the flip flop 380, which is high except when the trigger is activated to initiate an injection; the output of the inverter 356, which is high until the charge on capacitor 348 reaches a critical value;

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and the output conductor of the reference oscillator. When enabled, the output signal of AND gate 338 turns the FET 340 on and off at the rate  $F_H$  of the reference oscillator. When the transistor 340 is on, current will flow from positive potential through inductance 342 and the transistor 340 to ground. When the transistor 340 is subsequently turned off, the energy stored in the magnetic field of coil 342 will discharge through the path which is comprised of diode 344 and capacitor 348. The resistors 350 and 352 are of relatively high value; therefore, very little energy is lost in the path to ground through those two resistors. The magnitude of the voltage generated by the collapse of the magnetic field of coil 342 is very high and is dictated by the rate of collapse of the field. The rate of collapse is determined by the impedance of the discharge path. The diode 344 prevents reverse flow of current due to the buildup of voltage on the capacitor 348. Capacitor 346 is a stabilizing capacitor which provides an extra measure of current for the coil 342 during the ON state of transistor 340. When the charge and corresponding voltage on capacitor 348 reaches a predetermined value the output of the threshold detector 356 will go low and gate 338 is disabled. The predetermined value represents a charge and voltage large enough to advance the motor 221. When the output of detector 356 goes low, the output of inverter 358 goes high to enable transistor 360 to provide a path for discharging the capacitor 348 through the winding of motor 221. As the charge is depleted and the voltage on the capacitor falls below the threshold value of detector 356, the output of detector 356 goes high to enable gate 340 to initiate another cycle of charging capacitor 348; and the output of inverter 358 goes low to disable transistor 360. High speed charging cycles will continue until the flip flop 336 is set to the "1" state which indicates that the energy stored in spring 227 has reached the target value. In the drawing, the output labeled  $Q_1$  is the "1" output of the flip flop 336 and the complement output is termed the "0" output herein.

The energy enhancement technique of the Figs. 14A, 14B embodiment allows for a power source that has neither the voltage or current capability for directly driving the motor. However, if the power source has a voltage level that satisfies that of the motor, but whose electrical current capability is insufficient, then the drive embodiment of Fig. 15 can be used. In this case, energy enhancement still applies, but the voltage amplification provided by coil 342 and diode 344 are eliminated and the corresponding

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loss in efficiency is eliminated as well. Instead, when all conditions for an injection are satisfied, gate 338 activates transistor 340 so that capacitor 348 is charged to the voltage level of the battery; that is, the mid-point of divider 350/352 is adjusted so that Schmitt trigger logic inverter 356 will change state when battery voltage is achieved on capacitor 348, and immediately thereafter, the motor is driven with closure of transistor 360 as described for the Figs. 14A, 14B embodiment. This scenario provides a high speed, high energy, albeit lower voltage, sequence of drive pulses to the motor. Capacitor 348 is selected to provide sufficient electrical current for a long enough time to exceed the design value for motor advancement.

Fig. 16 shows an embodiment whose power source has enough instantaneous energy to drive the motor directly, i.e., one with enough current and voltage capability for driving the motor with no energy enhancement at all. In this case, transistor 340, coil 342, diode 344, capacitors 346 and 348, divider 350/352 and Schmitt inverters 356 and 358 are all eliminated. With this embodiment, the output of gate 338 will now drive transistor 360 so that the motor is connected directly to the power source when all conditions for an injection are met. A prototype of the "direct drive" system with a 9 volt alkaline battery achieved more than 400 injections in excess of 1700 psi each. With this arrangement, load time per injection is only 10 seconds; however, load time can be increased or decreased with variations in motor size, gear ratio, power capability and/or target pressure. It is also noted that for the same system, over 1,000 injections are achieved when using a higher energy density lithium battery.

While all of the jet systems described herein are smaller, lighter in weight and more convenient to use than those of the past, the selection of one drive technique as opposed to another is dictated by economics, acceptable load time and the primary use for the injector. For example, the Figs. 14A, 14B approach is the most compact because the total energy enhancement described will allow for a smaller motor/battery combination, however, it is also the least efficient and will result in fewer "shots" for a given amount of initial energy. A good example for this system is its daily use by diabetics where load time is not so critical and where it is easily carried in a woman's purse or a gentleman's pocket. When the maximum number of injections is paramount, such as mass immunization by the military, veterinary, DNA or agricultural procedures, then a better choice is the other end of the spectrum as shown in Fig. 16,

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that is, using a larger, direct drive motor, with lower voltage, higher efficiency and faster load time.

Finally, because of the wide adaptability of the inventive system, some applications might use motors with very high start-up current and/or free-wheeling  
5 rotors. If this is the case, the motor is ideally driven with an optional, electrically driven, clutch or gear engagement. In this way, the inertia achieved by the rotor at start-up is preserved by disengaging when capacitor 348 is charging, re-engaged when the next pulse of energy is given to the motor and will again disengage when completed. The entire sequence is conveniently controlled with the same signal that  
10 turns transistor 360 ON and OFF as capacitor 348 charges and discharges in the enhancement techniques of Figs. 14A, 14B and 15. When this is done, the signal to transistor 360 is synchronously delayed so that the mechanical linkage is optimally engaged at the same time that the energy stored in capacitor 348 is released into the motor. The feature can also be used with Fig. 16, but its advantage is not as great  
15 because, in this case, once started, the motor stays on until target pressure is achieved.

Regardless of the method used for driving motor 221, flip flop 336 is controlled by the  $A_N$  output conductor of counter 322, by an output signal of the digital window decoder 386, and by the BT conductor. The flip flop 336 is set to the "1" state when the  $A_N$  output of the counter 322 goes high if the BT conductor is high; and is reset  
20 by the output conductor of the decoder 386. Counter 322, in turn, is controlled by the  $F_{dl}$  signal at the output of flip flop 320 and by the output of flip flop 362. Flip flop 362 is set by a  $F_{dl}$  signal at the output of flip flop 320 and reset by a  $B_n$  output signal of counter 364. Counter 364 defines a period of time in terms of pulses of the reference frequency  $F_n$  and counter 322 counts the difference frequency pulses  $F_{dl}$ .  
25 Since counter 364 and counter 322 are reset at the same time by an output signal of flip flop 362, counter 364 provides a measurement window of time which runs from reset time to the next reset time. The  $A_N$  output conductor will remain low until the deformation of the spring 227 reaches the target value. When the counter 322 reaches the  $A_N$  count within the measurement time window, flip flop 336 is set and gate 338  
30 is disabled. At the same time, the "1" output of flip 336 is transmitted to the warning function 388 to indicate that the device is ready for an injection procedure. Flip flop 336 can be set only if the "BT" input to the "D" terminal of that flip flop is high. As

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will be explained with respect to Fig. 18, the BT conductor will be high if the bellows test is satisfactory. The digital code which is stored in counter 322 during a measurement time interval corresponds to the instant deformation of the energy storage spring 227. The digital pulse decoder 324, in response to the digital code in counter 322, generates input signals for the BCD counters 326, 328. For example, if the deformation of the spring which is equivalent to one pound of force on the spring provides ten cycles of differential frequency  $F_{dl}$ , decoder 324 will convert the code in counter 322 to a single pulse for BCD counters 326, 328. With a count of one in the counters 326, 328, the BCD decoders 330, 332 provide signals to the display 334 to display the value, one pound. Any number can be displayed with appropriate decoding by pulse decoder 324. By virtue of the display 334, the operator knows that the appropriate level of energy is stored in the spring 227 and that an injection may be initiated. The flip flop 336 remains set until an injection has been successfully completed. If the velocity test fails, a warning in 388 will issue and flip flop 336 will not be reset. Accordingly, remedial action must be taken before preparation for another injection can be started.

The power on switch 375, in the lower left portion of Figs. 14A, 14B, connects positive potential to the input of inverter 379 through the contact segments 370 and 371, detents 232 and 233, and line 377. The contact segments 370 and 371 lie in the recesses 108 on the back plate 104 shown in Figs. 1 and 2. When the trigger is operated, the detents 232 and 233 are disconnected from the contact segments 370 and 371; and, because the input is referenced to ground through resistor 374, the output of inverter 379 goes high. A high signal from the output of inverter 379 increments a counter in 390 to display the number of injections completed from the current bellows; and causes the "D"-type flip flop 380 to be set to the "1" state. Consequently, the "0" output of flip flop 380 goes low which disables AND gate 338. The high signal on the "1" output of flip 380 enables AND gate 382 to pass  $F_{dl}$  difference frequency signals to the input of counter 384. As explained earlier herein, the difference frequency will be reduced accordingly as spring 227 comes to some predetermined value after an injection. The count which is accumulated in the counter 384 is thus representative of the time required for the injection chamber to be partially collapsed. The window decoder 386 evaluates the count in the counter 384 on the basis of the

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expected values established by IC 2. If the count is larger than the expected limits, it is probable that the output port is plugged, and if the count is smaller than the expected limits, it is probable that the output port is enlarged beyond acceptable limits. In either event, a warning signal is displayed by the warning indicator 388 and the flip flop 336 will not be reset until remedial action is taken. If the count in counter 384 is within limits, an output signal of digital decoder 386 will reset flip flop 336 and the BCD counters 326 and 328. When that occurs, the cycle to drive the motor to load energy into the spring 227 will begin again. The time required for the chamber to partially collapse is short compared to the time required for the detents 232 and 233 to again settle in the recesses 108 and reconnect positive potential to the input of inverter 379. This time relationship is positively assured if a dashpot is employed to slow the return as suggested earlier herein. When the positive potential reappears at the input of inverter 379, capacitor 376 and resistor 378, which are configured as a high-pass filter, produce a reset pulse to flip flop 380 and counter 384 in preparation for the next injection. In the event that a very large volume injection is to be performed, the time required to inject the fluid may exceed the time for the detents 232 and 233 to settle in recess 108. In that case the illustrative high-pass reset circuitry can be replaced with circuitry with appropriate delay.

Fig. 18 provides an arrangement for testing the integrity of the liquid-filled bellows 404 or any other type of fluid-filled cartridge. Inverters 400 and 402 are configured as an oscillator in which the output frequency  $F_b$  is determined by the impedance across the entire bellows 404. Inverters 410 and 412 are configured as a fixed frequency oscillator having a frequency  $F_{r2}$ ; and flip flop 420 is connected as a frequency mixer for the signals  $F_{r2}$  and  $F_b$ . In the configuration of Fig. 18, the collapsing bellows behaves as a variable resistance; therefore, the frequency of the mixer output signal  $F_{d2}$  is minimum when the bellows is full. As the bellows collapses, the impedance decreases and the differential signal  $F_{d2}$  increases. The counter 422 accumulates the  $F_{d2}$  signals during a measurement time interval defined by the "0" output conductor of flip flop 362 of Figs. 14A, 14B, and pulse decoder and display 424 displays bellows status information. The use of the time period provided by the  $D_N$  count is for purposes of illustration. In the event that a different time period is desired, additional counter outputs and flip flops are provided. The arrangements of

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424 evaluate the interval count in counter 422 on the basis of the IC set 3 information which defines a range or window of acceptable values. If the count falls within the range of acceptable values, a high BT signal will be generated and flip flop is set on occurrence of the next succeeding  $A_N$  signal from counter 322. However, if the serum  
5 within the bellows has excessive voids, clots or an incorrect consistency for some other reason, the  $F_b$  frequency will fall outside the acceptable range and the count in 422 will fall outside the preselected window of performance.

It should be noted that fluid may be used as a dielectric material in an alternative embodiment in which a variable capacitance determines the frequency  $F_b$ .  
10 In that embodiment the variable bellows is located at the position of the capacitor 408 and a fixed resistor placed at the position 404 in Fig. 18. In this case, the two ends of the bellows form the capacitor plates and the serum fluid is the dielectric material. As the length of the bellows decreases, the capacitance increases and the frequency  $F_b$  decreases.

15 Figs. 19 to 22 show a needle-type hypodermic injector in accordance with my invention in various stages in the use of the injector. The injector of Fig. 19 comprises a bellows 500 sealed with end cap and ram 510; a front housing 503; a rear housing 502; a pressure piston 501; a needle output port 508 with a flange 511; a bellows-shaped needle sheath 504; and a removable cap 507. Fig. 19 illustrates a fresh injector  
20 prior to use. As in the injector embodiment of Figs. 1 and 2, the support guide rings 116 of those figures may be employed in the embodiment of Figs. 19 to 22. The bellows 500 may contain a liquid serum or a lyophilized (freeze dried) vaccine. In the latter case, a liquid which is stored in the sheath bellows 504 is driven into the bellows 500 as described below herein. The bellows 500, the rear housing 502 and the front  
25 housing 503 all may be fabricated of clear plastic material so that the operator can observe whether or not blood is drawn into the bellows 500 when the pressure piston is slightly withdrawn.

The breakaway seal 512 and the cap 507 are removed to permit the operator to depress housing 502. The need to remove the cap 507 may be eliminated if the cap  
30 507 is made of a self-sealing material, e.g., pure latex rubber. Typically, the thumb is placed on the pressure piston 501 and index finger and the adjacent finger are placed on the flange 511. The resistance of the sheath bellows 504 is sufficient to cause the

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bellows to expand after use; however, the resistance of the bellows 504 is small compared to the force required to compress the liquid bellows 500 to eject the liquid through the needle output port. Therefore, as pressure is applied between the flange 511 and the pressure piston 501, the sheath bellows will begin to collapse and needle exposure will begin. As the sheath bellows is collapsed, the right-hand side 520 of needle 506 will puncture the membrane separating sheath bellows 504 and serum bellows 500. As compression continues, the liquid residing in sheath bellows 504 is forced into serum bellows 500 to form the fluid state of the desired serum. Ultimately, needle flange 505 will engage the surface 514 therein, after removal of breakaway seal 513. Continued pressure will force the serum in 500 to be expelled through the exit port of needle 506, said serum being unable to re-enter 504 because it has collapsed to zero internal volume. A foam ring 516 positioned on the right side of flange 505 serves as a cushion to prevent flange 505 from opening the membrane to a greater extent than that of puncture point 520. The membrane in 500 also can be made of self-sealing latex diaphragm material which will tend to hold the needle in place after the injection is completed and the sheath is again extended to cover the needle. The first intermediate state of the injector is illustrated in Fig. 20:

In cases where the serum is stored in bellows 500 in a liquid state, the bellows 504 can be replaced with a simple coil spring. However, if as suggested earlier herein, the vaccine is stored in the lyophilized state, the fluid required to turn the vaccine to the liquid state is stored in the bellows 504. In this latter case, the liquid in bellows 504 is forced into bellows 500 through a hole in the membrane of the bellows 500 which is breached when the bellows 504 is first compressed to begin exposure of needle 506.

After the needle is inserted into the injection site, the breakaway seal 513 is removed and pressure is applied between the pressure piston 501 and the flange 511 to collapse the liquid bellows 500 and eject fluid through the output ports into the injection site. The state of the injector after depletion of the injection fluid is illustrated in Fig. 21. As shown in Fig. 23, a sawtooth pattern 518 on the outer surface of the pressure piston 501 and a single sawtooth 517 on the inner surface of the rear housing 502 permit the pressure piston 501 to be advanced into the member 502 and thus compress the bellows 500. However, the cooperation of 517 and 518 prohibits

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withdrawal of the piston 501 after engagement of 517 and 518. As an option, the end of the ram 510 is shaped to strike and crush the end 520 of the needle 506 when the bellows 500 is fully collapsed. This will further assure that the needle injector cannot be reused and will tend to retain the needle in engagement with the bellows 500 when  
5 the sheath bellows 504 and the sheath 503 are extended to cover the needle.

After the needle is removed from the subject and pressure between 501 and 511 is removed, the bellows 504 expands as shown in Fig. 22. As is seen in Fig. 22, when the needle sheath bellows 504 extends to its full length, the needle 506 is withdrawn from the needle guide 508. This occurs because, in preparation for the injection, end  
10 520 of needle 506 penetrated the membrane to breach the serum chamber. Because the needle guide opening 508 is small compared to the trap opening 509, it is difficult if not impossible to again collapse the bellows 504 without the end of the needle 506 hitting the end wall 515 of the trap section 509. The tendency of the needle to hit the wall 515 can be enhanced by imparting a small bend in the needle 506 prior to initial  
15 installation into the guide opening 508.

The above discussion for Figs. 19 to 22 deals with the various steps for a special case insertion of a hypodermic needle into an injection site. Capsules 5A to 22 and needle 506 can also provide several other valuable functions. First, if the housing is designed to fit into a jet injection chamber similar in nature to that of Fig.  
20 25, needle 506 issues the highly desirable dispersion pattern of a jet injection stream much deeper into the body. This capability provides superior medical treatment in some cases. Second, if needle 506 is shortened to exit the capsule to the appropriate length, it will deliver lyophilized medications while deriving all of the advantages of a perforator jet injection. Third, if needle 506 is made even shorter by the correct  
25 amount, it will not exit the housing at all, but instead, the capsules 5A to 5D will serve as a non-penetrating, flat, prior art orifice, similar to that shown in Fig. 43 but capable of delivering a lyophilized jet injection to humans or thinner-skinned animals.

Fig. 25 shows an alternative embodiment of a jet injector system in which the serum for each and every injection is individually contained in its own collapsible  
30 cartridge. A dispenser 700 includes a handle 911 from the forward end of which extends a trigger 701. A muzzle 913 includes at its rearward section a lever 702 extending laterally through a longitudinal slot 915 in muzzle 913 which terminates at

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its forward end in a downward extending portion 917. Dispenser 700 includes at its forward end a receptacle or opening 919 for receiving a cartridge 800 holding a serum for injection into a recipient. Dispenser 700 includes a piston or ram 703 for acting on cartridge 800 to effect an injection. Cartridge 800 is described below and shown in Figs. 37 and 38.

For illustrative purposes, the cartridge 800 shown in Fig. 25 is grossly oversized, wherein a normal injection requires from 1/2 to 1 cc of serum (from about .031 to .061 in<sup>3</sup>) and the actual cartridge size is commensurate with that volume. Since the system of Fig. 25 can be proportioned to handle single-shot or multiple-shot cartridges, the smaller size is also true for the magazine embodiment of Figs. 26 and 27, that is, the illustrative magazine is many times larger than that needed for the N cartridges shown in the figures. For a single-shot arrangement, the lever 702 is drawn to the rear to permit removal of a used cartridge from receptacle 919 and a fresh cartridge installed. After a fresh cartridge is installed, the lever 702 is moved forward, to the left in Fig. 25.

With regard to the magazine embodiment of Figs. 26 and 27 in which the N cartridges 800 are serially introduced into system 700, which is shown identical to that in Fig. 25, many magazine configurations are possible for sequential loading into and out of the injection chamber. For example, much in the manner of a modern pistol with a linear magazine containing N bullets or, the revolver-type weapon in which the bullets rotate into the chamber or, as shown in the oversized preferred embodiment of Figs. 26 and 27, there is shown the entire magazine 921 which is simply detented through opening 919 in the injector chamber as each new injection occurs. In this latter arrangement, the cartridges are not extracted at the completion of each injection, but simply remain in magazine 921. This feature is especially important for the prevention of unsafe littering at the scene of mass immunization programs such as the military or activities of the World Health Organization in their worldwide efforts with disease control. Other methods of collection and storing the used cartridges are also possible, for example, a magazine that has an evacuated volume equal to that of the loaded cartridges, and into which the used cartridges will drop at the conclusion of an injection.

A manual advance for the magazine can be implemented with lever 702 or an

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automatic advance is realized with a spring configured ratchet assembly that is "wound up" when magazine 921 is slipped into the bottom opening of the dispenser 700 and urged upward until latched into the initial position for the injection sequence. Since the system is electrical in nature, a motor advance is the most convenient of all; however, power conservation for a multitude of high pressure injections has a higher priority in many applications. As discussed earlier, any suitable driving force can be utilized to drive pressure piston 703 forward to collapse the serum chamber 804 in cartridge 800 (as explained below) when said cartridge appears at the injection site.

Switch 375 is basically the ON-OFF switch for system power. The manner in which the power is provided can be carried out in a number of ways, wherein the one or more ways selected is normally dictated by the application and/or user preference. Several embodiments are described below.

Referring to Figs. 14A, 14B for one such way, switch 375 is simply turned ON, after which flip flop 336 automatically enables gate 338 and turns ON motor 221; when target pressure is detected, flip flop 336 disables gate 338. This cycle continues until a system failure occurs or the injection capability is depleted. In a single or multiple cartridge system, the detent action of contacts 232, 233 is provided as part of the trigger mechanism 701 in Figs. 25, 26 and 27.

Turning to Figs. 26 and 27 for another embodiment, momentary switch 372 in Fig. 17 replaces the latching contacts 232, 233. Switch 372 could be temperature sensitive and would only be enabled if a temperature threshold is reached. Moreover, switch 372 also can only be enabled if an access code is entered, as for example by an access key. Switch 375 still provides primary power to the system, but switch location 372 will remain open until all of the following requirements are met: (1) the magazine is securely positioned in the dispenser, after which switch 372 closes as it engages the first cartridge through slot 373 in the wall of magazine 921, (2) switch location 372 is enabled when the user applies pressure to guard ring 103 or 805 when the ring is brought into firm contact with the injection site, (3) the temperature threshold is met, and (4) the access code is entered. These features provide additional levels of safety by preventing accidental firing of the injector until the user is ready and/or prevents use by illicit drug users or other unauthorized people. In the case of temperature, damage is prevented to the injector or user when the injectant, whose viscosity is

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temperature-dependent, is too thick to allow for a safe and timely passage through the small diameter orifice under the influence of very high pressure. Other embodiments of switch location 372 are also possible and will depend on the level of safety required for a particular application.

- 5           A MANUAL/AUTO select is provided in another embodiment, wherein the manual mode switch location 372 is actuated by the user rather than by the cartridge, the guard ring or temperature detector in the AUTO mode. However, the AUTO mode is also provided, as described in the preceding paragraph.

- 10           When the magazine and cartridge embodiment is used, counter and display function 390 will electronically measure and display the number (shown as 926 in Figs. 26 and 27) of "live" cartridges actually found in the magazine. The counter and display number will then proceed with a countdown to zero as the cartridges are used. Again, this feature is important for situations where a magazine is removed and then returned to the dispenser for a later round of injections.

- 15           It is clear that in the magazine-type system, the expended cartridges can be safely disposed of; however, for purposes of economy in certain situations, the magazine can be ruggedly built for multiple long term use, in which case the entire magazine can be returned to a center for disease control, sterilized and reused in whole or in part. In one such embodiment, the cartridges themselves are reusable, but the  
20           exit nozzle is removed and replaced in the same manner as described for the multiple-dose cartridge of Figs. 1 and 2. If the magazine is reusable, a preferred embodiment of this feature has the cartridge counter, its processor, display and a power source ideally located right in the magazine. With this embodiment, no count initialization is necessary because it simply detects the live cartridges found in the magazine on a  
25           real time basis whether the magazine is in the dispenser or not. In fact, this technique is useful for other magazine-oriented applications such as pistols, shotguns, rifles and automatic or semi-automatic weapons of any type. For such a system, a low battery warning would be used with the independent counter system as well. A specially designed version of the reluctance transducer and processor described for Figs. 14A,  
30           14B is ideally suited for this embodiment.

Finally, as pointed out earlier, it is noted that a dispenser similar to that of Fig. 25 can be used for the needle oriented cartridge of Figs. 19-23. Further, if the Figs.

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19-23 cartridge is designed into the magazine structure of the Fig. 26 dispenser, then N needle-type cartridges can be administered in much the same way as the jet injector embodiment, but with greater efficiency and speed than that of the individual cartridges, while still providing the highly desirable dispersion pattern of a jet stream, and with even less risk to the population because the entire magazine remains under the watchful eye of the immunization team. As in the case of the Figs. 19-23 embodiment, the jet injector of Figs. 25, 26, 27, 28, 39, 30, 31, 37 and 38 can be fabricated of clear plastic material so that the operator can observe if the needle has penetrated a blood vessel after insertion, but prior to expelling the fluid. This is possible by virtue of an automatic micro-withdrawal of the pressure piston under the influence of the monitoring and control sequence of the electrically driven system.

Figs. 28, 29 and 30 offer alternatives to Figs. 26 and 27 by allowing for a rechargeable power source and an even larger multi-shot system. Typical applications are veterinary and agricultural uses where the multiple-shot cartridge system is replaced by serum container 962, or for use at remote locations where grid power is not available..

Viewing Fig. 28, the correct dose of serum 960 is pulled out of container 962 through connecting tube 965 and into the injection head through access nipple 966. This will occur each time the ram is pulled back in preparation for the next shot, wherein every dose is administered through the same orifice 969. For veterinary use in particular, the periodic (sometimes daily) administration of the BST hormone to a herd of dairy cows becomes a very efficient procedure. With this scenario, serum container 962 is pre-loaded with the correct number of doses and is then carried by the user on waist or shoulder harness 970 as shown in Fig. 29, and the entire herd can be quickly inoculated. Also shown in Fig. 29 is an additional fluid container 963 with a dye material that is transported to exit nozzle 967 through connecting tube 964. Especially useful for the injection of large animals in close proximity to each other, an appropriate amount of dye is drawn into the dye chamber at the same time serum is drawn into its chamber. The dye is expelled and deposited at the injection site as an indicator to show which of the animals has been injected with a particular material. This feature will prevent the adverse effects no injection at all or having an animal receive the same material more than once.

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In Fig. 28, power pack 950 is inserted and removed from access port 954 of the jet injector housing, wherein electrical contact 952 connects power to the injector. With this approach, the number of shots available from each source is not quite so critical, whereas it would be inconvenient for members of an immunization team, health care, agricultural or veterinary workers to repeatedly change and dispose of the battery. All they have to do is carry a number of sources in a storage harness, change them as each is depleted, and then have the entire group recharged with solar energy for isolated areas or a standard AC or DC source at more convenient locations.

Finally, power adapter 968 in Fig. 30 can be inserted into the injector housing in place of power pack 950 to allow for operation from other power sources if the portability of small battery operation is not required. For example, adapter 968 can be connected directly to an adequate source of external power or to power pack 972, wherein the injector is then powered with a non-disposable source of external energy that is transported to the remote location along with the injector, the medications and the health worker units. External source 972 can be a high capacity rechargeable battery or a storage capacitor whose value is large enough to supply N shots before recharge is needed. Recharge of power pack 972 can come from grid power at socket 976 (if available), or as an alternative, a solar panel trickle charger 978, a portable generator 980 or directly from a vehicle's power system 982 if such vehicle is available to the health care workers. In some remote locations, powerful solar systems 983 located nearby or on the roof of the health care facility are also conveniently used.

An injector system 703 of Fig. 31 illustrates a form-fitted, barrel-like restraining chamber 705 and a cooperating door 708 which together provide the support needed for a high pressure injection with an inexpensive, thin-walled capsule 820. Capsule 820 can have a wall thickness of from .01 inch to .05 inch. These capsules 820 are discarded after each injection in the same manner as the disposable needle and syringe, except that the inconvenience, danger and cost of disposal for needle injections are eliminated. In this embodiment, injector 703 has a cylindrical barrel 707 defining chamber 705 and having a door 708 forming part of the barrel and mounted on a hinge 709. To load a capsule, door 708 is opened and capsule 820 inserted into restraining chamber 705. An access groove 710 accommodates and supports the guard ring end 103 of capsule 820. This end of capsule 820 also has a non-slip surface 901 as well

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as exit orifice 109. After capsule 820 is inserted, door 708 is secured in the closed position with a latch 712. The form-fitting chamber 705, a lip 714 on door 708 and groove 710 work together to hold capsule 820 securely in place to prevent any damage during the high pressure injection. A spring loaded arm 716 having a spring 717  
5 attached to the interior of barrel 707 is compressed when the capsule is inserted and ejects the capsule when door 708 is opened; thus, physical contact and the risk of cross-infection for the health worker is further reduced when the injection is completed. Other parts of the injection system similar to those of the apparatus of Fig. 30 are given the same reference numerals.

10 The Fig. 32 embodiment has good utility with large scale injection programs for animals and is an alternative to the replaceable capsule. Subsystem 830 is a low cost combination comprising serum sack or chamber 832, connecting passageway or tube 834 and thin-walled injection capsule 836 all supplied as a single unit. When a particular medication is given to a herd of cattle, serum sack 832 is filled with the  
15 selected medication and inexpensive capsule 836 is inserted into the highly restrained injection chamber 705 of injection system 703. When the injection procedure is completed, the entire subsystem 830 is removed and stored for future use or discarded. This system will avoid the problem of gumming-up the injector for situations and/or locations that make it inconvenient to clean the device in a timely manner as, for  
20 example, for large numbers of feed cattle on the range or when they just come in for treatment.

Figs. 33 and 34 show a capsule or injection barrel 840 intended to illustrate two different embodiments of an injection head with multiple exit ports. In the first case shown in Fig. 33, a set of multiple exit ports 842 provide a number N jet stream of a  
25 fluid 843 from a single serum chamber. This technique has utility for advantageously reducing injection time for very large doses, sometimes in excess of 5cc for large animals such as cows. With small exit ports on the order of .004 to .012 inch as required for a high velocity, piercing jet stream, the amount of time needed to discharge the fluid with a single port is quite long, up to three seconds, giving the  
30 animal ample opportunity to move before the injection is completed. This first embodiment is intended to avoid that problem.

The second embodiment is shown in cut-away form in Fig. 34 and is useful



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where discharge time is not a factor, for example for smaller human doses in the order of 0.5 to 1.0cc. However, for this case, the multiple exit port configuration has even greater utility for injecting more than one vaccine into the injection site at the same time. This is especially important for children where repeated use of needle injections is frightening, painful and very often difficult to complete because of adverse physical resistance, as well as the added expense of return visits to the health center or doctor's office. This type of patient reaction could lead to inadequate vaccinations and the possibility of unnecessary exposure to some very dangerous diseases. The multiple exit port solution makes use of a number N parallel, independent, barrel-type restraining chambers, one of which is shown as 845 in the cut-away view of barrel 840. Included in each of restraining chambers 845 is a different, inexpensive, thin-walled vaccine capsule and its exit port 842' that rests against a mating hole 838 in a forward access disk 844, shown as a broken out structure in Fig. 34. These capsules are similar to that described for Fig. 31, but thinner in diameter to facilitate the side-by-side orientation. Each of the N capsules has its own piston 847 which interfaces with N geometrically matching rams 848 appended to a single central ram 849. Ram 849, and each of rams 848 moves to the left as shown in the drawing, pushing pistons 847 inward with the correct force when released from its position of stored mechanical energy. This configuration allows the health worker to rapidly dispense all injectants at the same time so that pain, fear, expense and resistance to injections are all dramatically reduced. In the description of Fig. 26 and 27, it was noted that a multiple chamber system similar to a revolver type pistol could be used for housing the vaccine capsules. The capsules can be loaded in the configuration of Fig. 34 by sliding barrel 840 forward to expose the N mating carriages into which capsules 846 are inserted. The form-fitted outer portion of barrel 840 is then slid back into position to securely lock capsules 846 in place until the injection is completed. A trap door similar to door 708 described for Fig. 31 can also be used. Capsules 846 can be prefilled by the vaccine manufacturer and shipped to the health center, or they can be filled by the health worker with the appropriate vaccine when the person shows up for the injection. If jet or needle capsules of the type described for Figs. 19-23 are used, lyophilized serum can also be administered simultaneously with either the needle or jet orifice embodiment.

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The multiple capsule system of Fig. 34 and 35 has further utility by providing for different injection depth from each of the N injection chambers. This is accomplished by simply making a small change in the cross-sectional area of each of the capsules and its piston 847. Since central ram 849 will apply the same force to each of the independent rams 848, chamber pressure will depend on the cross-sectional area of the piston to which the force is applied. If this is done, slight changes in capsule does will occur since the distance of travel for all rams is the same because of their dependence on central ram 848. By the same token, the risk of error could be reduced because the containment chambers 845 can also have cross sections that will only accommodate a predetermined capsule. However, if consistent dose is an issue, further flexibility for injection depth is realized with slight modification to the diameter of the jet orifice for each capsule to facilitate a change of stream velocity for the known force, and injection depth will vary accordingly. Finally, different penetration depth for each capsule will help keep the injection products farther apart in the tissue, which in some cases is an important factor.

Fig. 36 illustrates a robotic system 850 for use with cattle 856 that are automatically identified and cut from the herd when an injection procedure is scheduled. The robotic system includes a control box 851 and an articulated, movable, mechanical arm 852 composed of injectant delivering tubes. This is a convenient time to mechanically restrain the animal, wherein arm 852 will move into position so a perforator 854 can contact the animal for a subsequent injection. The anchor point provided by the perforator is especially useful for a good injection because energetic movement by the animal is very likely at this time.

Further utility is provided if arm 852 of robotic system 850 is removable to provide a mobile, extended-arm injection system. A long, mobile injection system of this type will facilitate long range injections of large animals. This situation often arises if the animal is restrained at the neck, but requires an injection at a posterior portion of the body. The device is also useful when numerous animals are penned up, are in close proximity to each other, and are often lying down. For these situations, an extended arm on the order of one meter long will help simplify the injection procedure.

The cartridge 800 is shown in detail in Figs. 37 and 38. Cartridge 800

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comprises a sealed serum bellows 804 with a ram 803; a rear housing 801; a pressure piston 802; a front housing 812, which comprises a guard ring 805 and a jet output port 807 with a flange 808; and removable cap 810. Fig. 37 illustrates a fresh injector installed in the system of Figs. 25, 26 or 27 prior to breaching the seal of serum bellows 804. As described elsewhere herein, cartridge 800 can be configured with a  
5 needle or perforator for delivery of the serum.

Fig. 38 illustrates the arrangements of Fig. 37 after the lever 702 of Fig. 25 is moved forward to breach the seal of the bellows 804 and to bring the injector piston 703 in position to drive the pressure piston 802 forward to collapse the bellows 804.

10 Figs. 39-43 show the hide or dermis 860 of an animal such as a cow overlaying the subcutaneous space or layer 862, which in turn lays over a muscle 864. Dermis 860 has a thickness D and subcutaneous layer 862 has a thickness S. Fig. 39 illustrates the "pooling" effect that occurs when a capsule is used with a conventional needle and comprises an injection assembly 870 including a capsule 871, a cylindrical housing 872  
15 and a plunger 874. A conventional hypodermic needle 876 is operatively connected to capsule 871, which holds an injectant 878. When plunger 874 is depressed, injectant 878 is ejected through the exit port of needle 876 and forms a pool 861 in muscle 864. Pooling often provokes an attack by the animal's immune system, thereby causing an encapsulation of the medication which often leads to abscesses and/or  
20 serious scarring of the tissue. In the case of feed animals, damage to the meat causes a significant economical loss to the industry, and in some cases, will provoke a level of infection that renders the animal useless.

Fig. 40 illustrates an injection assembly 880 having capsule 871 with housing 872 and plunger 874. A perforator 882 has a surgically sharp tip 883 at its delivery  
25 portion, and is attached to capsule 871 and enclosed with a collapsible protective housing 884. Perforator 882 has an attachment portion 914 for attachment to capsule 871. Collapsible housing 884 is in the form of a bellows having a free end 886 with walls 888 defining a circular opening 890 with a diameter larger than that of perforator 882. Housing 884 has an opposite end 892 which is fixed to the base of capsule 871.

30 Referring to Fig. 41, a detailed description of perforator 882 is shown. The perforator is of tubular construction, preferably made from stainless steel, having an effective length of no greater than the thickness of the dermis and subcutaneous layers

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of the skin or hide as discussed below. It has a slanted, surgically sharp tip 911 for being inserted into the skin or hide to provide a jet injection as explained hereinafter. Perforator 882 has a longitudinal, central axis L, and the slanted tip 911 has an oblong opening 913 with a central axis L' transverse to axis L. The slanted opening assists in preventing the delivery of foreign matter into a body during an injection with perforator 882. The slanted tip creates an anchor point to establish and maintain the penetration position of the delivery portion of the needle. It further maintains laminar flow of the jet stream emanating from the perforator, even if there is movement of the body being injected.

10 In Fig. 42, perforator 882 has been inserted into hide 860, but its tip 883 falls just short of the subcutaneous layer 862. Perforator 882 has an effective length X for insertion into the body having dermis 860, subcutaneous layer 862 and muscle 864 for an intramuscular or subcutaneous injection. Length X is less than the sum of thicknesses D and S of dermis 860 and subcutaneous layer 862 so that it does not enter muscle 864 during an injection. Plunger 874 has been depressed and housing 884 has been collapsed against hide 860, and the injectant discharged to yield the penetrating jet stream 894 which will then deposit a vast majority of the injectant in the target area of the muscle 864, if that is the desired target, while leaving virtually none in the hide 860. If a subcutaneous injection is needed, one simply must reduce the injection pressure so that the jet stream will penetrate the remainder of the hide while not having enough energy to successfully penetrate the muscle.

Finally, while this entire discussion has focused on perforator advantages for an intramuscular injection, both veterinary and human immunologists have cited experimental evidence indicating that injections into the dermis may be many times more potent than that of the IM or subcutaneous regions, so much so, in fact, that greatly reduced volumes of the injectant may be possible. If continued research in this regard leads to a recommendation that certain injections be given in the dermis, the perforator concept is remarkably effective for this application as well, and actually provides additional advantages over that of the needle and syringe. To assure a perforator intradermal injection, one must simply shorten the length X so that it penetrates the outer layer while at the same time falling short of the subcutaneous space. In addition, if the pressure is reduced to the appropriate level, experimental

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work by the inventor on a freshly euthanized cow has shown that all of the injectant will remain in the dermis, with none at the surface, while also spreading the injectant over a much wider radius than that experienced with the pooling effect of the prior art needle and syringe. As with the IM or subcutaneous injection, the increased area and  
5 volume covered by the injectant will provide an increasingly rapid and effective pick-up by the immune system.

Fig. 43 illustrates the jet stream coming from a conventional prior art flat injection orifice. An injection assembly 896 includes capsule 871 with housing 872 and plunger 874, and a flat jet orifice 897. When plunger 874 is depressed, a jet  
10 stream 898 is emitted, and beginning from the outer surface of the hide 860, the tough, hairy and often dirty conditions immediately often cause degradation of stream 898 so that a high percentage of the injectant remains on the outside, with very little, and in many cases, none of the injectant reaching subcutaneous space 862 or muscle 864, resulting in a much less effective injection, even if a dermal injection was intended.

15 Fig. 44 is an alternate embodiment of the invention showing perforator 882 from Figs. 40 and 42, but with a different orifice. In this case, a high quality, smaller diameter orifice 899 is located at the entrance end of perforator 882. When the jet injection is initiated, it will travel down the middle of perforator 882 without touching the walls and before encountering any of the animals hide or flesh. The very high  
20 quality, high coherency of such a flow pattern 900 will allow for much deeper muscle penetration with even less of the injectant being left behind in the dermis 860 or subcutaneous layer 862 if the objective is an intramuscular injection.

Fig. 45 shows injection system 880 with a high quality orifice 902 connected to the injection chamber of housing 872, and having an externally threaded connector  
25 ring 904 affixed thereto. A perforator 906, similar to perforator 882 but having an internally threaded entrance end 908 for engagement with the threads on connector ring 904. The threaded connection between connector ring 904 and perforator 906 provides for an easy change of perforator 906 by simply unscrewing perforator 906. Other fast connect-disconnect devices can be used as well. The system emits jet stream 900 as  
30 noted with respect to Fig. 44.

System 800 in Fig. 46 is similar to that in Fig. 44, except that the high quality orifice 899 is located at the exit end of perforator 882.

Finally, Fig. 47 illustrates an adaptation derived from the perforator concept. In this embodiment, small diameter exit tube 907 extends about 2 to 4 mm from injector housing 871 and is configured with a non-sharpened, flat ended output. This diagram is not shown to scale and is drawn primarily for illustrative purposes. With  
5 this embodiment, there is no initial perforation, but it was found that the short protrusion will move aside any hair and both stretch and provide a detent at an injection site 909 when surface contact is made. Significant improvements in jet penetration is realized, while at the same time reducing the amount of injectant left at the surface as opposed to that of the prior art flat orifice of Fig. 43. Benefits are  
10 found for human injections, for thinner hides of young calves and for other thin-skinned animal applications such as cats, dogs, fowl, etc.

The illustrative embodiments of our invention which are disclosed herein are but representative of our invention and many changes in form and function can be made without departing from the spirit and scope of our invention.

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What is claimed is:

1. A collapsible body having a holding means for holding a hypodermic fluid for injection, said body having needle means for injecting the hypodermic fluid once sufficient pressure is applied to said body to collapse said body to force fluid  
5 from the holding means and through said needle means.
2. A collapsible body according to claim 1 and further including second holding means for holding a second ingredient for injection, said needle means being located in one of said holding means and said second holding means and positioned to penetrate the other of said holding means when sufficient pressure is applied to said  
10 body to cause said fluid and said second ingredient to be brought together.
3. A collapsible body according to claim 1 wherein said second holding means is bellows shaped.
4. A jet injector for injecting one or more fluids into a body from one or more capsules holding the fluid, the capsule(s) having walls defining an outer  
15 configuration, an inner cavity for the fluid and an exit port for discharging fluid from the capsule when a predetermined pressure is applied to the fluid in the capsule, said jet injector comprising:  
one or more barrel means for selectively receiving and releasing one or more capsules, said barrel means having a barrel wall defining an interior configuration  
20 configured for operatively engaging the outer configuration of the received capsule, said barrel wall having sufficient strength to withstand the predetermined pressure applied to the fluid in the capsule to discharge fluid from the capsule and restrain the capsule against damage, said barrel means having stop means for preventing the projection of the capsule from said barrel means upon the application of the  
25 predetermined pressure to said capsule means, said stop means having an exit defining a path for flow of the fluid discharged from the exit port of the capsule.
5. A jet injector according to claim 4 wherein said barrel means further includes:  
one or more ram means movable towards the one or more received  
30 capsules for exerting pressure on the capsules received in said barrel means;  
biasing means actuatable from a set condition for applying sufficient force on said ram means to move said ram means against the received capsule to apply the

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predetermined pressure on the capsule to discharge fluid through the exit port as a jet stream; and

control means for releasing said biasing means from said set condition.

6. A jet injector according to claim 4 wherein said control means comprises  
5 release means having a holding condition for holding said biasing means in said set condition, and trigger means for removing said release means from said holding condition to release said biasing means from said set condition.

7. A jet injector according to claim 4 wherein each of the capsules includes  
10 a piston for applying pressure to the fluid in the capsule, and wherein said ram means is movable in response to the release of said biasing means for engaging and moving the piston to apply the predetermined pressure on the capsule.

8. A jet injector according to claim 4 wherein said biasing means is at least one spring.

9. A jet injector according to claim 7 wherein said spring is a  
15 precompressed spring.

10. A jet injector according to claim 7 wherein said spring is a coil spring.

11. A jet injector according to claim 7 wherein said spring is an elastomeric spring.

12. A jet injector according to claim 1 wherein the capsule has a generally  
20 cylindrical outer configuration, and said barrel wall defines a tubular inner configuration for engaging the outer configuration of the capsule.

13. A jet injector according to claim 4 wherein said jet injector injects at  
least two fluids into a body from capsules holding the respective fluids, and wherein said barrel means comprises barrel means operatively associated with the respective  
25 capsules.

14. A jet injector according to claim 4 wherein said jet injector injects at  
least two fluids into a body from capsules holding the respective fluids, and said barrel means includes

- a set of ram means movable towards the respective received capsules to  
30 apply the predetermined pressures on the respective capsules received in said barrel means;

biasing means actuable from a set condition for applying sufficient



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forces on the respective ram means to move said respective ram means against the respective received capsules to apply the predetermined pressures on the respective capsules to discharge fluid through the exit port of the respective capsules as jet streams; and

5 control means for releasing said biasing means from said set condition.

15. A jet injector according to claim 4 wherein said jet injector injects at least two fluids into a body from capsules holding the respective fluids, and wherein the respective capsules each include a piston for applying pressure to the fluid in the capsules.

10 16. A jet injector according to claim 4 wherein said jet injector injects at least two fluids into a body from capsules holding the respective fluids and wherein said barrel means comprises barrel means operatively associated with the respective capsules, and wherein the respective capsules each have a generally cylindrical outer configuration, and said barrel wall of said respective barrel means each define a tubular  
15 inner configuration for engaging the outer configuration of the respective received capsule.

17. A jet injector system for injecting fluid into a body, said jet injector system comprising:

20 capsule means for holding the fluid, said capsule means having side walls and a capsule end wall defining a tubular cavity for the fluid, said side walls being rigid and having an exterior configuration, said capsule end wall having exit port means for discharging fluid from said capsule means when a predetermined pressure is applied to the fluid in said capsule means;

25 barrel means for receiving said capsule means, said barrel means including:

a barrel wall defining an interior configuration configured for operatively engaging the exterior configuration of said capsule means, said barrel wall having sufficient strength to restrain the predetermined pressure applied to the fluid in said capsule means to prevent expansion of said capsule means to prevent damage to said capsule means and upsetting of the fluid flow,  
30 when fluid is being discharged from said capsule means;

a discharge end interfacing said capsule end wall of said received

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capsule means; and

stop means on said discharge end for preventing said capsule from being projected from said barrel means when said pressure is applied to said capsule means, said stop means having exit means for defining exit for the flow of fluid discharged from said capsule means;

one or more ram means movable towards said capsule means for exerting pressure on the fluid in said capsule means received in said barrel means;

biasing means actuatable from a set condition for applying sufficient force on said ram means to move said ram means against capsule means received in said barrel means to apply predetermined pressure on said capsule means to discharge fluid through said exit port means as a jet stream; and

control means for releasing said biasing means from said set condition.

18. A jet injector system according to claim 17 wherein said control means comprises release means having a holding condition for holding said biasing means in said set condition, and trigger means for removing said release means from said holding condition to release said biasing means from said set condition.

19. A jet injector according to claim 17 wherein said capsule means further includes piston means movable with said side walls towards the fluid, and wherein said ram means is movable against said piston means in response to the release of said biasing means from said set condition for moving said piston means to apply said predetermined pressure on said capsule means.

20. A jet injector according to claim 17 wherein said biasing means is at least one spring.

21. A jet injector according to claim 20 wherein said spring is a precompressed spring.

22. A jet injector according to claim 20 wherein said spring is a coil spring.

23. A jet injector according to claim 20 wherein said spring is an elastomeric spring.

24. A jet injector system according to claim 17 wherein said side walls of said capsule means are thin, said side walls being frangible if sufficient pressure is exerted on the fluid held by said capsule means to discharge the fluid as a high velocity jet stream without the restraint of said barrel means on said capsule means.

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25. A jet injector system according to claim 17 wherein said side walls of said capsule means have a thickness of between .01 inches and .05 inches.

26. A jet injector according to claim 14 for injecting at least two fluids into a body, wherein said capsule means comprises a capsule for holding the respective  
5 fluids, and said barrel means comprises barrel means for each of the respective capsules.

27. Apparatus for injecting fluid into a desired section of a body having an outer dermis, an inner muscular region, and a subcutaneous region between the dermis and the muscular region, the dermis having a thickness D which can vary for different  
10 types of bodies at the location where an injection could be made, and the subcutaneous region S being variable for each type of body at locations where an injection could be made, said apparatus comprising:

perforation means for perforating and entering the dermis of the body, said perforation means having an effective length L for insertion into the body, said  
15 length L being less than the sum of thicknesses D and S, said length L preventing said perforator means from perforating the muscular region, and

entrance port means having an inlet for receiving the fluid and an outlet for dispensing the fluid, said inlet receiving the fluid under high pressure and said  
20 outlet dispensing the fluid at pressures and velocities of sufficient magnitude to generate a jet stream for penetrating the desired region of the body.

28. Apparatus according to claim 27 wherein said perforator means comprises an attachment portion for attachment to a supply of the fluid, and a delivery portion for perforating the dermis and conducting the jet stream of the fluid into the  
25 desired region of said body, said delivery portion having a longitudinal axis, said outlet of said entrance port means being located on said delivery portion and having a central axis slanted relative to the longitudinal axis of said delivery portion for enabling said delivery portion to penetrate the dermis and create an anchor point to establish and maintain the penetration position of said delivery portion, and maintain an effective fluid flow of the jet stream even if there is movement of the body being injected.

29. Apparatus according to claim 27 wherein said perforator means comprises an attachment portion for attachment to a supply of the fluid, and a delivery  
30 portion for perforating the dermis and conducting the jet stream of the fluid into the

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desired region of said body, said delivery portion having a surgically sharp end for piercing the dermis and a longitudinal axis, said outlet of said entrance port means having a central axis slanted relative to the longitudinal axis of said delivery portion for preventing the insertion of foreign matter into the body when said delivery portion  
5 pierces the body.

30. Apparatus for injecting a fluid into a desired region of a body having a difficult-to-penetrate and injection-resistant outer layer, an inner region, and an intermediate region separating the outer layer and the inner region, the outer layer having a thickness  $D$  variable for different types of bodies at locations where an  
10 injection could be made, and the inner space having a thickness  $S$  variable for different types of bodies at locations where an injection could be made, said apparatus comprising:

perforation means for perforating and entering the outer layer of the body, said perforation means having an effective length  $L$  for insertion into the body,  
15 said length  $L$  being less than the sum of thicknesses  $D$  and  $S$ , said length  $L$  preventing said perforator means from perforating the inner region, and

entrance port means having an inlet for receiving the fluid and an outlet for dispersing the fluid, said inlet receiving the fluid under high pressure and said outlet dispensing the fluid at pressures and velocities of sufficient magnitude to  
20 generate a jet stream for penetrating the body and disbursing the fluid in the desired region of said body.

31. Apparatus according to claim 30 wherein said perforator means comprises an attachment portion for attachment to a supply of the fluid, and a delivery portion for perforating the outer layer and conducting the jet fluid stream into a desired  
25 region, said delivery portion having a longitudinal axis, said outlet of said orifice means being located on said delivery portion and having a central axis slanted relative to the longitudinal axis of said delivery portion for enabling said delivery portion to penetrate the outer layer and create an anchor point to establish and maintain the penetration position of said delivery position, and maintain an effective fluid flow of  
30 the jet stream even if there is movement of the body being injected.

32. Apparatus according to claim 30 wherein said perforator means comprises an attachment portion for attachment to a supply of the fluid, and a delivery

portion for perforating the outer layer and conducting the jet stream of the fluid into a desired region, said delivery portion having a surgically sharp end for piercing the outer layer and a longitudinal axis, said outlet of said entrance port means having a central axis slanted relative to the longitudinal axis of said delivery portion for preventing the insertion of foreign matter into the body when said delivery portion pierces the body.

33. Apparatus according to claim 30 wherein the perforator means comprises a short elongated member having a length L designed to deposit a jet stream injection into the desired region.

34. Apparatus according to claim 30 where the outer layer has a tough outer surface covered with outwardly extending hair or other material tending to convert laminar fluid flow towards the outer layer into a turbulent stream of the fluid rendering it ineffective to pierce the outer layer, and wherein said perforator means comprises a delivery portion having a longitudinal axis, and said outlet of said perforator means has a central axis slanted relative to the longitudinal axis to enable said delivery portion to penetrate the outer layer and prevent the insertion of foreign matter into the body and maintain laminar flow of the fluid into the body.

35. A jet injection system for injecting materials into a body from one or more capsules holding the materials, said jet injection system comprising:

capsule holding means for holding a capsule during release of the material from the capsule;

jet injector means for applying release force to the capsule to release the material from the capsule as a jet stream for entering the body, said jet injector means having actuating means having an enabling condition for actuating said jet injector means to apply the release force to the capsule and a disabling condition for preventing said actuating means from applying the release force; and

security means for selectively putting said actuating means in the enabling condition or the disabling condition according to a predetermined condition.

36. A jet injection system according to claim 35 and further comprising splash guard means for engaging the skin or hide of a body to be injected to prevent splashing of the material during an injection, and said predetermined condition is the proper location of said splash guard means.

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37. A jet injection system according to claim 35 and further comprising temperature monitoring means for a temperature signal when the temperature is determined to be outside of certain temperature limits, and said predetermined condition is said temperature signal.

5 38. A jet injection system according to claim 35 wherein said security means comprises access means having a release device for selectively placing said access means in said predetermined condition.

39. A jet injection system according to claim 38 wherein said release device includes key means for selectively placing said access means in said predetermined  
10 condition.

40. A jet injection system according to claim 35 wherein said security system comprises code-operated access means, and said predetermined condition is the entry of the proper code into said access means.

41. A jet injection system according to claim 35 wherein said jet injector  
15 means is electrically powered.

42. An injection capsule holding injection material for use with a jet injection system, the jet injection system having capsule-holding means for holding a capsule during an injection process and force applying means for applying force to the capsule to eject injection material from said injection capsule, said injection capsule  
20 comprising side walls and end walls defining an interior chamber for holding the injection material and a plurality of exit port means having a plurality of exit ports for emitting injection material when the force applying means applies force to said capsule to eject the injection material.

43. A jet injection system for injecting material into a body from a capsule  
25 holding the material, said jet injection system comprising:

capsule-holding means for holding a capsule during release of the material from the capsule;

electrically powered jet injector means for applying release force to the capsule to release the material from the capsule as a jet stream for entering the body,  
30 said jet injector means;

electrical energy storage means for storing electrical power to energize said jet injector means; and

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recharge means for replenishing electrical energy removed from said electrical energy storage means.

44. A jet injection system according to claim 43 wherein said recharge means is a solar powered recharge means for receiving solar energy and converting the solar energy to electric energy for said electric energy storage means.

45. A jet injection system according to claim 43 wherein said recharge means comprises an electrical energy transfer system for transferring energy from the electrical energy storage means of a motor vehicle to said electrical energy storage means.

46. A jet injection system for injecting at least two materials into a body from capsules holding the respective materials, said jet injection system comprising:  
capsule-holding means for holding the respective capsules during release of the materials from the capsules;

electrically powered jet injector means for applying release forces to the respective capsules to release the material from the respective capsules as respective jet streams for entering the body, said jet injector means;

electrical energy storage means for storing electrical power to energize said jet injector means; and

recharge means for replenishing electrical energy removed from said electrical energy storage means.

47. A jet injection system for injecting at least one material into a body from an injection material container for each material, said jet injection system comprising:

jet injector means for supplying the respective injection materials from the respective containers; and

robotic arm means comprising articulated injection material conveying tubular arms positionable on the body to be injected, for injecting the injection materials from said jet injector means into the body.

48. A jet injection system for injecting at least one material from capsules holding the respective materials into a body, said jet injection system comprising:

a capsule holding the respective injecting material;

at least one exit port through which the injection material exits from the

respective capsules;

a perforator operatively connectable to said exit port for perforating the skin or hide of a body and for transmitting the injecting fluid from the capsule into the body; and

5 orifice means operatively connected to said exit port and defining an orifice for emitting the material as a jet stream through the perforator.

49. A jet injector system according to claim 48 and further including perforator connection means for connecting said perforator to said respective exit ports.

50. A jet injector system according to claim 49 wherein said orifice means  
10 is attached to said exit port and has external threads, and said perforator has an entrance end with internal threads for mating engagement with the threads of said orifice means to attach said perforator to said exit port.

51. A jet injector system according to claim 48 wherein said perforator has an entrance end and a discharge end, and said orifice means is located between said  
15 entrance end and said discharge end.

52. A jet injection system for injecting materials into a body from one or more containing means for the materials, the containing means discharging the materials as a jet stream when pressure of a predetermined strength is exerted on the containing means, said jet injection system comprising:

20 rotatable means for rotating to action said jet injection system;

thrust means movable for transmitting thrust force to exert the pressure of the predetermined strength on the containing means to discharge the materials and cause the injection to proceed, said thrust means including a thrust member operatively connected to and rotatable with said rotatable means, said thrust member being  
25 movable in response to a predetermined centrifugal force, and

centrifugal means operatively attached to said rotatable means for generating said predetermined centrifugal force when said rotatable means rotates at a predetermined rate of rotation.

53. A jet injection system according to claim 52 wherein said thrust means  
30 comprises plunger means movable for exerting the pressure of the predetermined strength to the container means, said thrust member being operatively connected to said plunger means and movable for transmitting the thrust force to said plunger means to



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cause said plunger means to exert said pressure of the predetermined strength, and flyweight means operatively connected to said rotatable means for rotating with said rotatable means and for generating said centrifugal force to move said thrust member to transmit the thrust force to said plunger means.

5           54.    A jet injection system according to claim 53 wherein said rotatable means comprises a rotatable spindle having an axis of rotation; said thrust member comprising a thrust rod operatively connected to said spindle and rotatable therewith; and said flyweight means comprises flyweights and arms attaching said flyweights to  
10   said spindle, said arms being movable from a position closer a parallel direction with said axis of rotation to a position closer to a radial direction with said axis of rotation as the injection proceeds.

          55.    A jet injection system according to claim 54, and further including thrust bearing means operatively connected to said thrust rod and to said plunger means, said thrust bearing means transmitting the thrust force from said thrust rod to said plunger  
15   means.

          56.    A jet injection system according to claim 52 and further including constant inertia means rotatable with said rotatable means for compensating for friction losses during operation of said jet injection system.

          57.    A jet injection system according to claim 52 wherein said jet injection  
20   system further includes latching means for reducing thrust load losses during acceleration of said rotatable means, said latching means comprising:

                  flange means mounted for rotation on said rotatable means;

                  axle support means extending in the direction of the longitudinal axis and being rotatable about the longitudinal axis;

25                blocking means in operative engagement with said flange means and mounted on axles transverse to and intersecting the longitudinal axis, said axles being supported in axial alignment in said axle support means, said rollers transmitting the thrust force against said thrust member;

                  lug means mounted on said thrust member for releasably engaging said  
30   blocking means for preventing movement of said thrust member along the longitudinal axis; and

                  release means selectively actuatable for releasing said lug means from

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engagement with said blocking means to enable movement of said thrust member along the longitudinal axis.

58. A jet injection system according to claim 57 wherein said blocking means are rollers, and wherein said release means comprises:

5 wedge means movable to disengage said rollers from said lug means, to enable movement of said thrust member along the longitudinal axis.

59. A jet injection system according to claim 58 wherein said release means further comprises:

10 ring means concentric with the longitudinal axis for supporting said wedge means in the direction of the longitudinal axis, said flange having slots and said wedge means extending from said ring means through said slots, and said ring means being movable along the longitudinal axis to move said wedge means to disengage said rollers from said lug means.

60. A jet injector system according to claim 59 wherein said release means  
15 further comprises trigger means for moving said ring means along the longitudinal axis.

61. A jet injector system according to claim 60 wherein said trigger means comprises:

20 a trigger member movable from a set position to an actuating position for moving said ring means to release said roller means from said lug means; and means for resetting said trigger member from said actuating position to said set position.

62. A jet injector system according to claim 61 wherein said trigger means further comprises solenoid means for moving said trigger member from the set position  
25 to the actuating position.

63. A jet injection system according to claim 52 and further comprising flyweight means operatively connected to said rotatable means for generating the centrifugal force to move said thrust member, and wherein said thrust member is rotatable on and axially movable along a longitudinal axis, and wherein said rotatable  
30 means comprises a motor rotatable spindle for rotating said flyweight means, and latching means for reducing thrust load losses during acceleration of said rotatable means, said latching means comprises:

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outer hydraulic cylinder means mounted on said spindle and holding hydraulic fluid;

inner hydraulic cylinder means mounted on said thrust member within said outer hydraulic cylinder and holding hydraulic fluid, said inner hydraulic cylinder means having end walls with fluid passages, and said outer hydraulic cylinder means opening and closing said fluid passages;

piston means mounted on said thrust member within said inner hydraulic cylinder means, said piston means and said thrust member imparting thrust force to the fluid; and

collar means for moving said inner hydraulic cylinder to open said fluid passage at one end of said one end of said inner hydraulic cylinder to effect the movement of said piston means to exert the thrust force.

64. A fluid injection system according to claim 63 and further including locking means releasably locking said latching means according to a release force, the relative movement of said inner and outer hydraulic cylinders being locked until a certain centrifugal force is attained.

65. A fluid injection system according to claim 64 wherein said release force for said locking means is adjustable.

66. A jet injector system according to claim 52 wherein the container means comprises a capsule for holding the injecting material, and said thrust means includes piston means for applying the pressures of predetermined strength on the capsule.

67. Apparatus for injecting material into a body, said apparatus including injection means for discharging the material for entry into a place on the body, and electrical pain suppression means for transmitting electricity to the place on the body to suppress pain at the place where the material enters the body.

68. Apparatus for injecting material into a body, said apparatus including injection means for discharging the material for entry into a place on the body, guard ring means for engaging the place on the body to maintain said injection means stationary with respect to the body, and electrical pain suppression means attached to said guard ring means to suppress pain at the place where the material enters the body.

69. A jet injection system for injecting fluid into a body as a jet stream, said jet injection system comprising:

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injection chamber means for the fluid, said injection chamber having fluid discharge means for injecting the fluid as a jet stream;

ram means for applying pressure on the fluid in the injection chamber to inject the fluid when a drive force is applied to said ram means;

5 drive means for applying the drive force to said ram means;

transducer means connected to said drive means for monitoring the value of the drive force and for generating a feedback signal reflective of the drive force;

control means electrically connected to said transducer means and to said drive means for comparing the signal reflective of the drive force to a target signal  
10 reflective of a target force, and for generating a control signal to said drive means to adjust the drive force towards the target force.

70. A jet injection system for injecting an injection material into a body from an injection material container and for applying a dye material to the body indicative of the injection material from a dye material container, said jet injection  
15 system comprising:

jet injector means for supplying the injection material from the injection material container into the body; and

dye material means for applying dye material on the body to indicate that the injection material was injected.

20 71. A jet injection system for injecting at least two fluids into a body from containers holding the respective fluids, said jet injection system comprising:

capsule-holding means for holding the respective capsules during release of the fluids from the capsules;

pressure applying means for applying a pressure to the capsules to  
25 discharge the respective fluids from the capsules; and

injection depth changing means for varying the depth at which at least two of the fluids are injected into the body, said depth changing means including a variation in the cross section of the areas through which the at least two fluids flow to the body.

30 72. For use with an injector having a barrel-like restraining chamber for receiving a capsule holding a dose of serum for jet injection into a body, a subsystem comprising a capsule having a discharge orifice, a multi-dose serum container and a

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connecting serum passageway interconnecting said serum container and said capsule, the injector applying pressure to said capsule to discharge a dose of serum from said capsule and a new dose being transferrable from said sack, through said connecting passageway and into said capsule, said subsystem being disposable or removed from  
5 the injector for storage for future use, to avoid the gumming up of the injector.

73. A jet injection system according to claim 52 and further including a latching system for starting the injection when said centrifugal means generates a centrifugal force equal to a predetermined value.

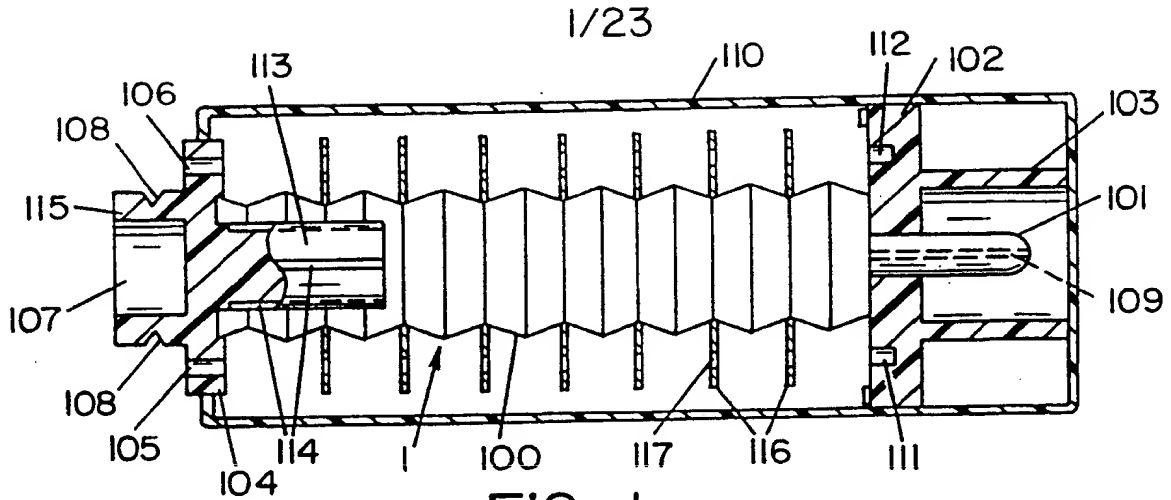


FIG. 1

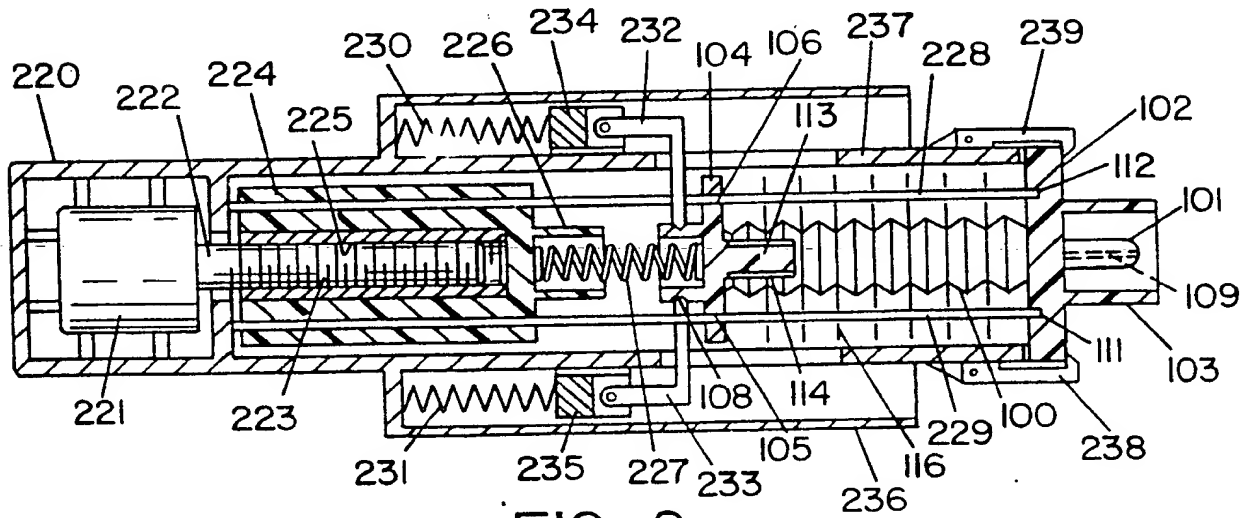


FIG. 2

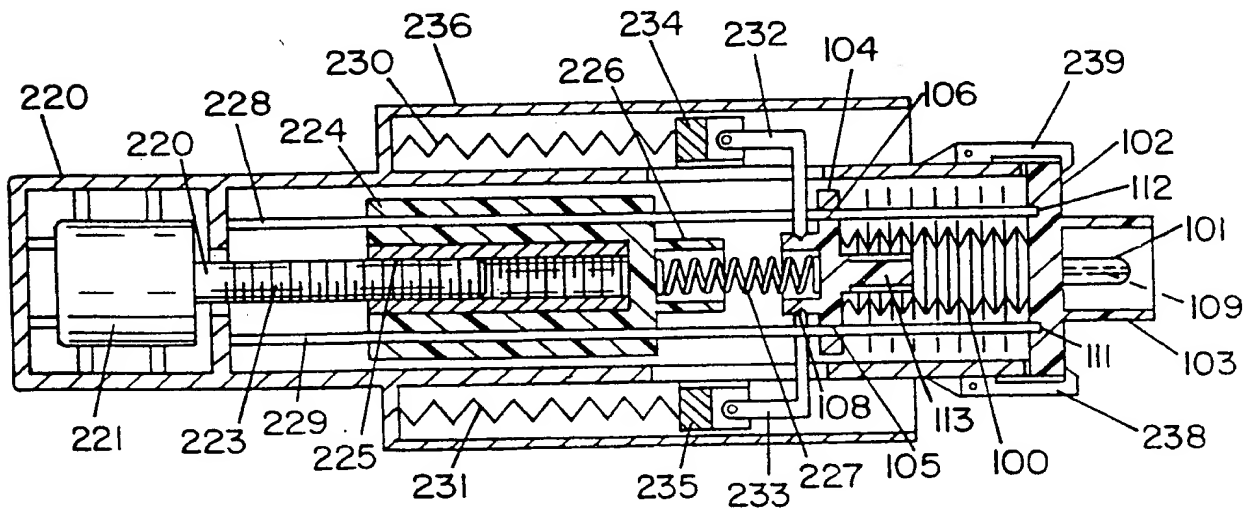


FIG. 3

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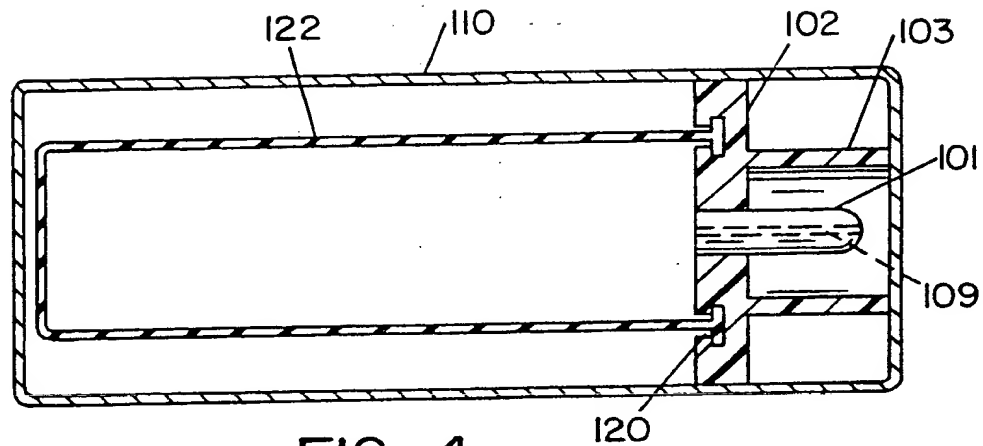


FIG. 4

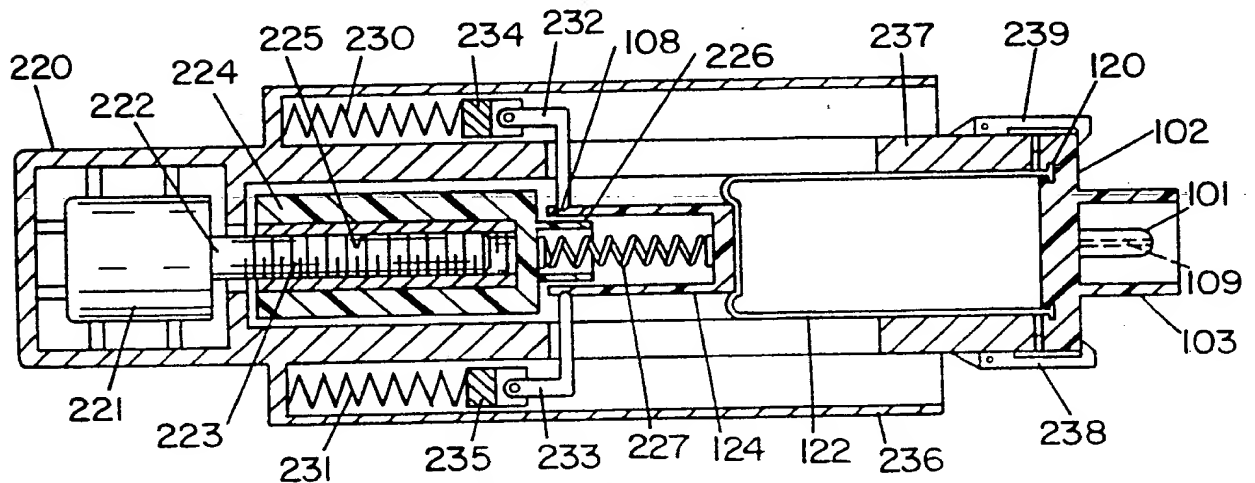


FIG. 5

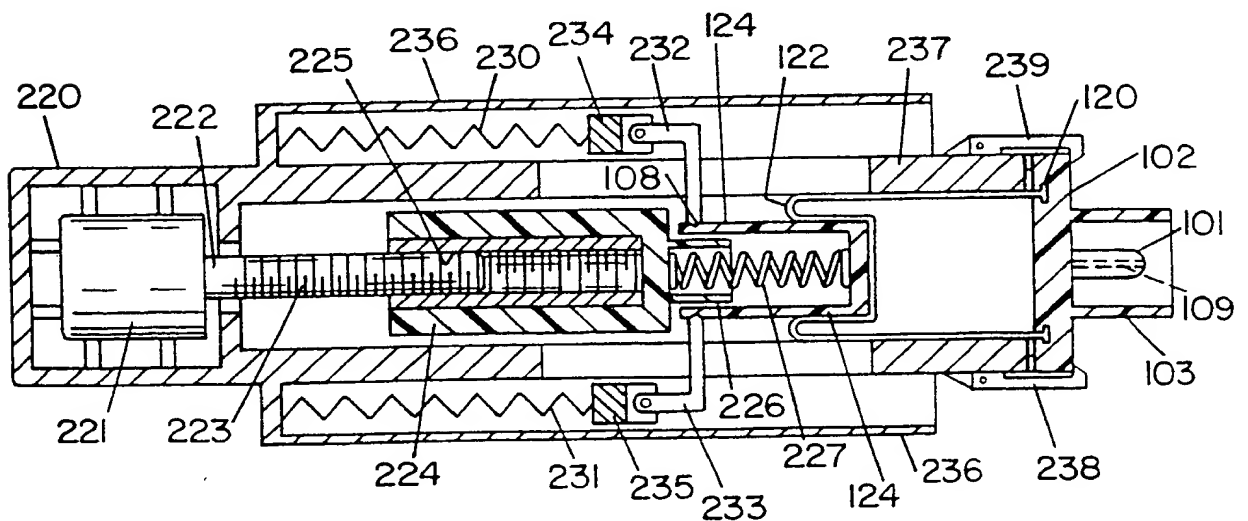


FIG. 6

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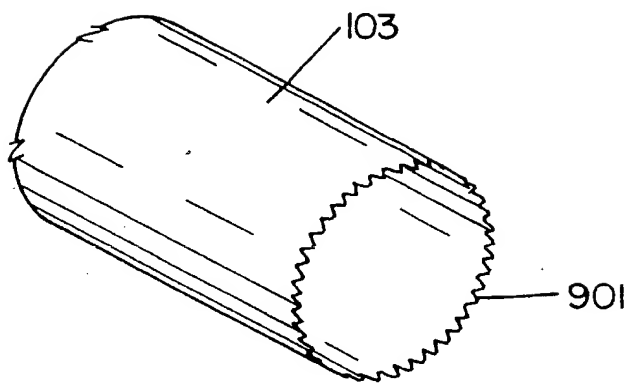


FIG. 7

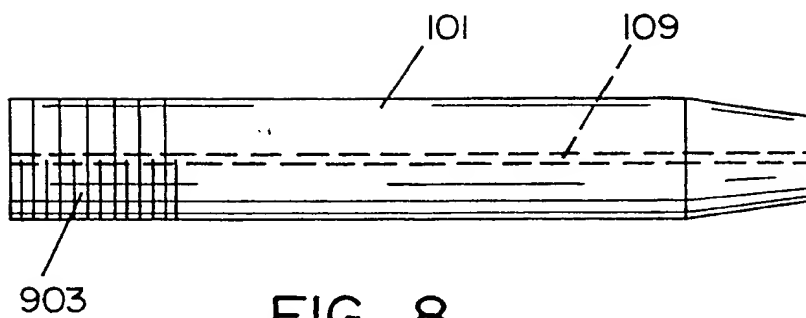


FIG. 8



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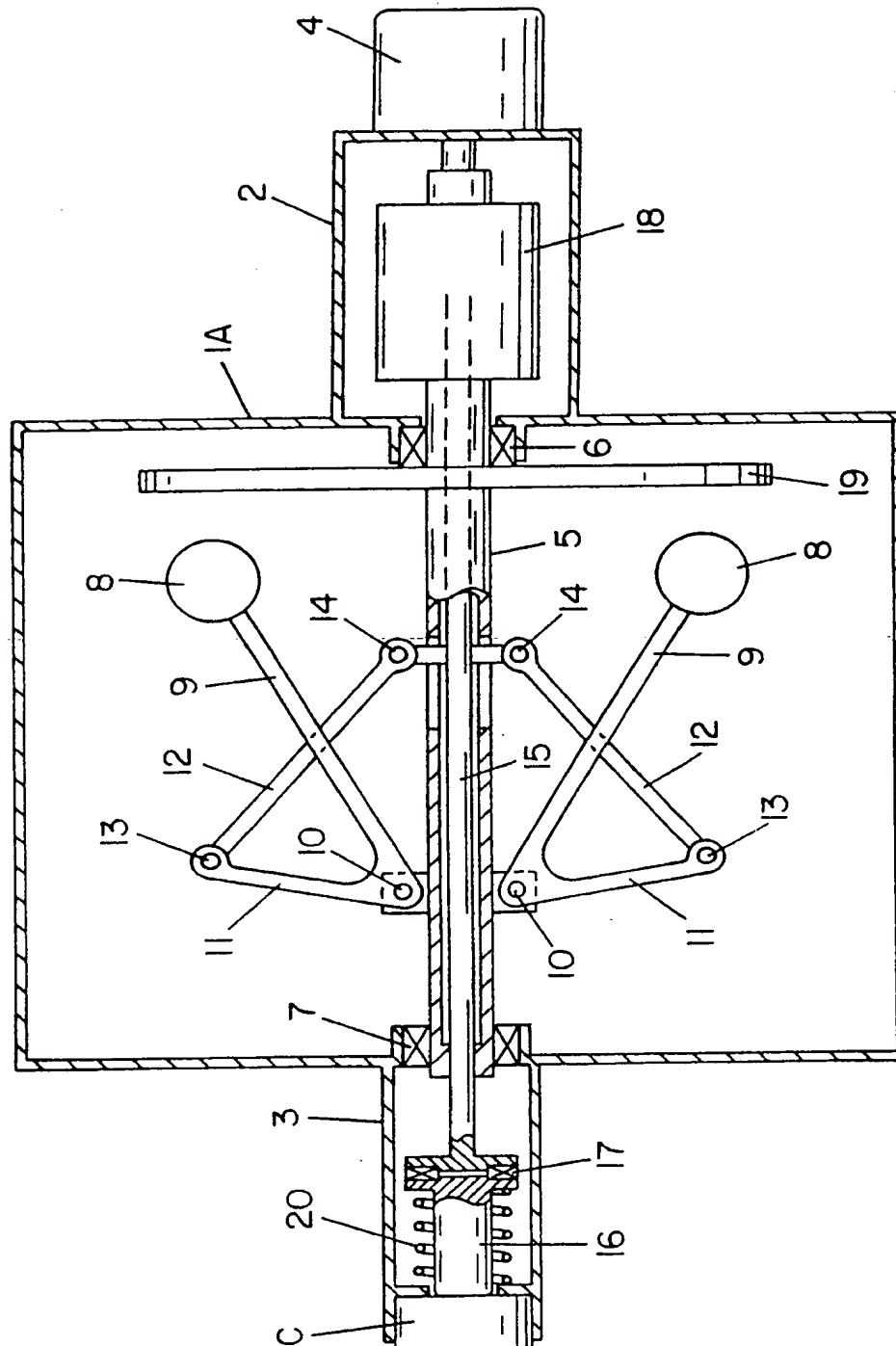


FIG. 9

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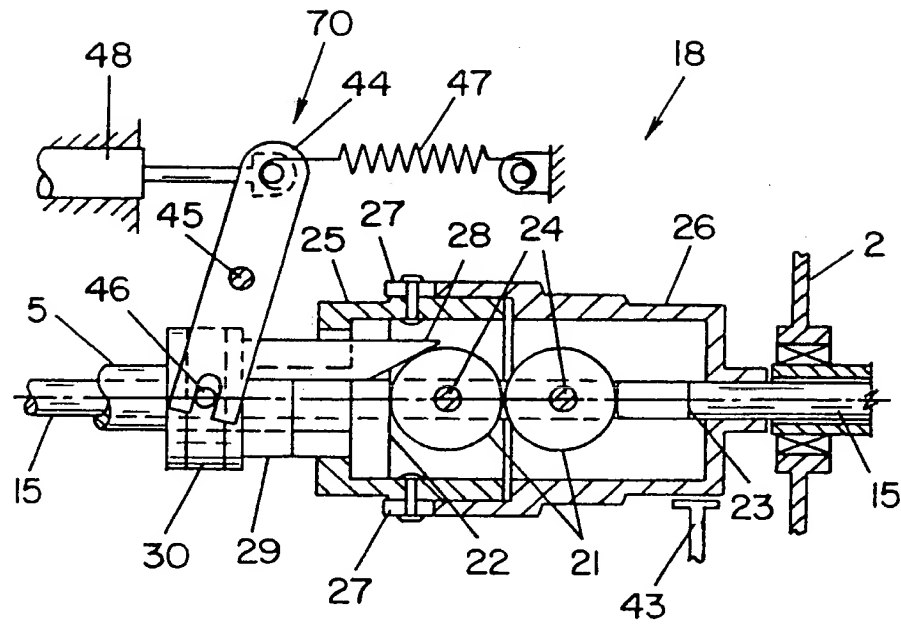


FIG. 10

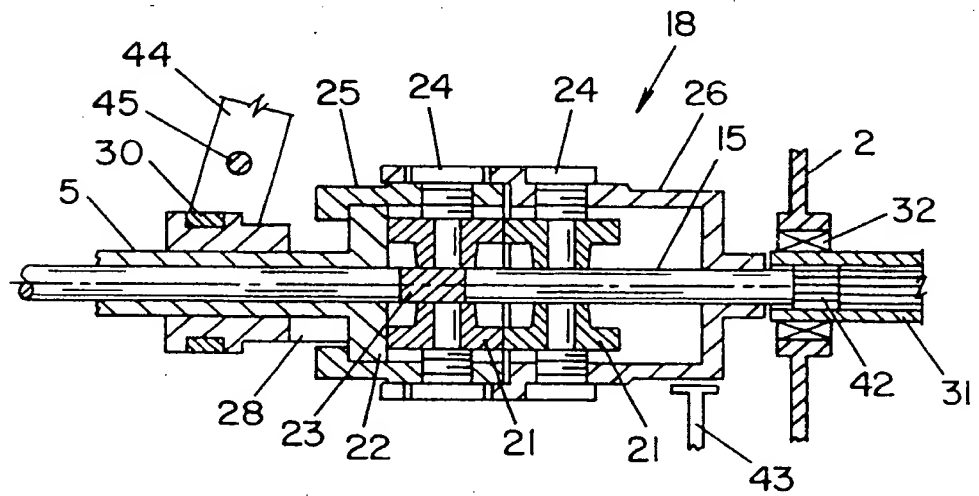


FIG. 11

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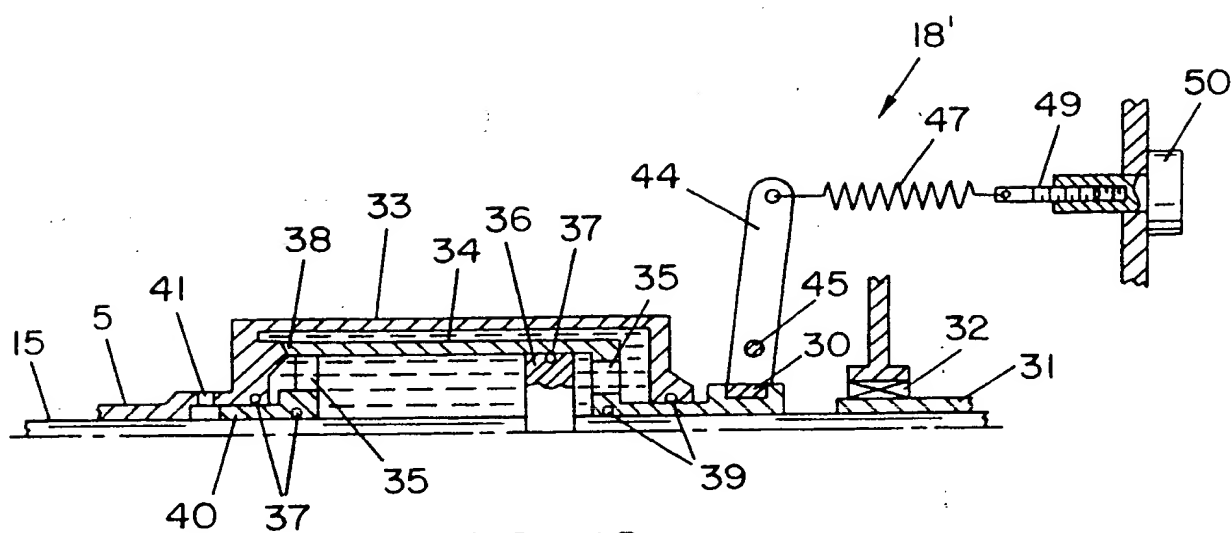


FIG. 12

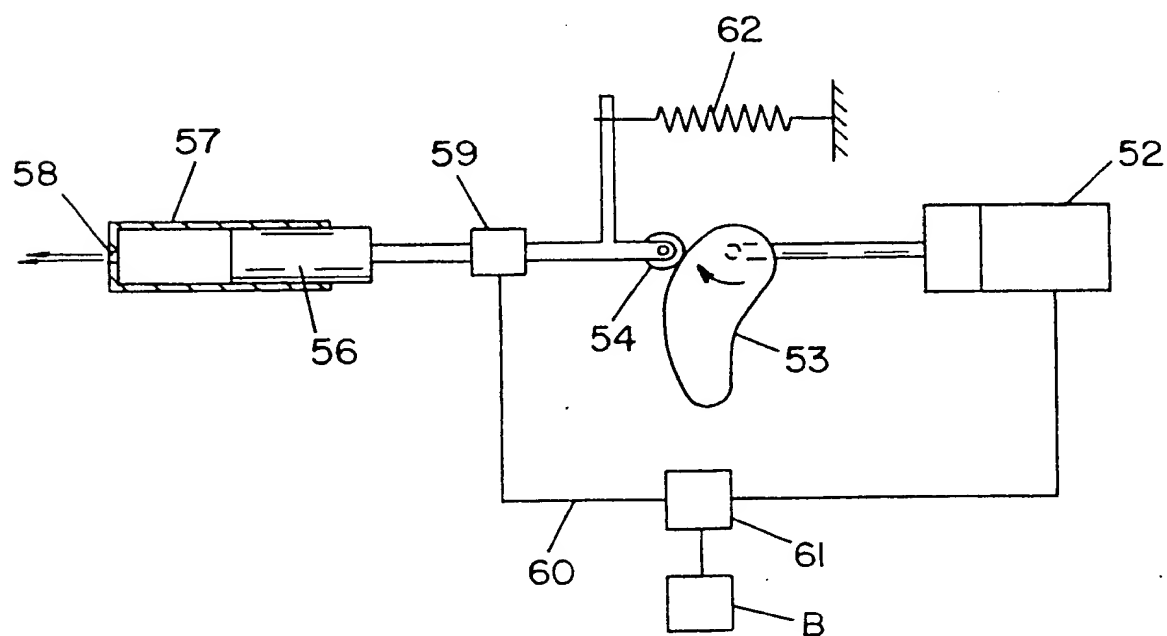
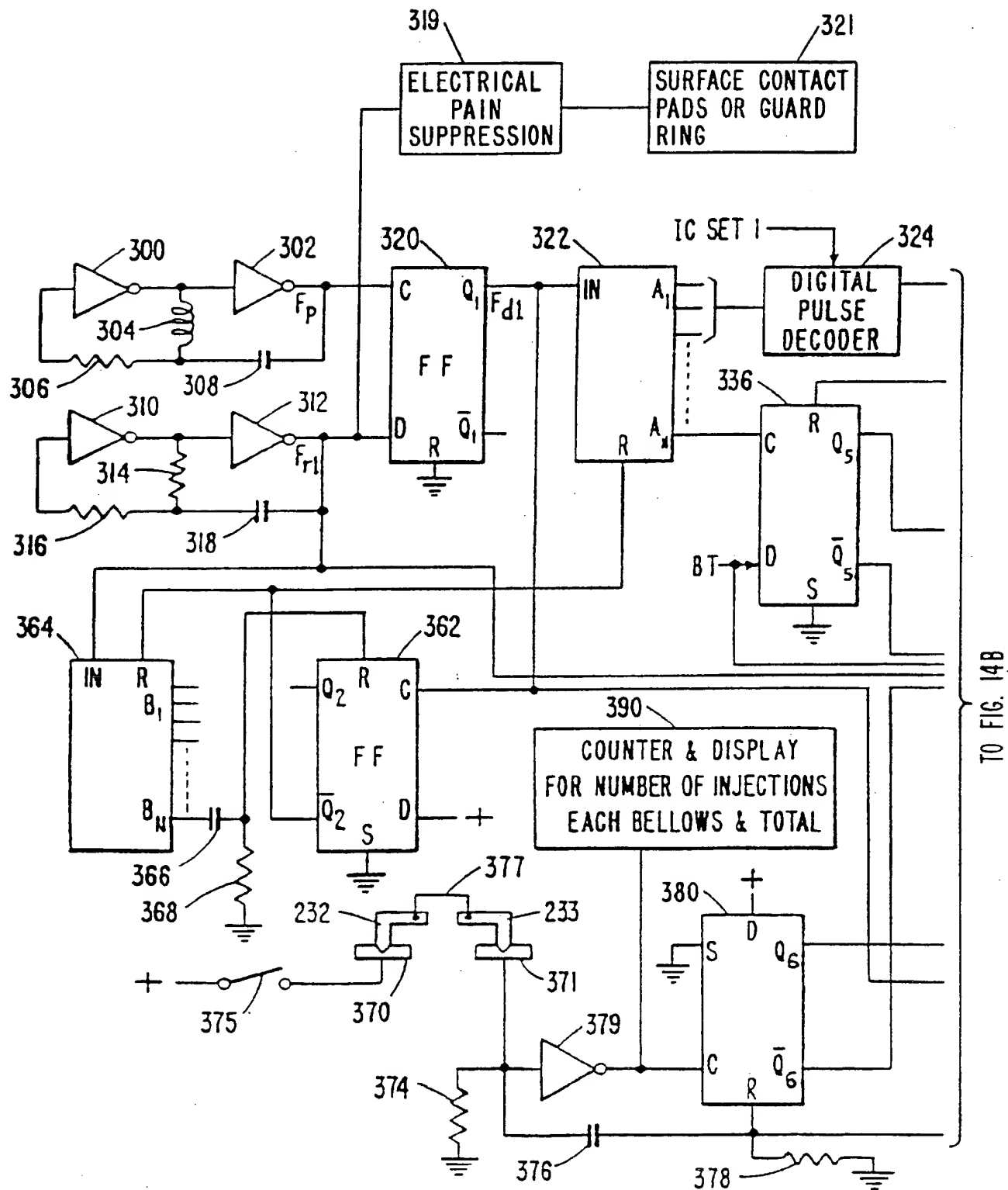


FIG. 13

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TO FIG. 14B

FIG. 14A

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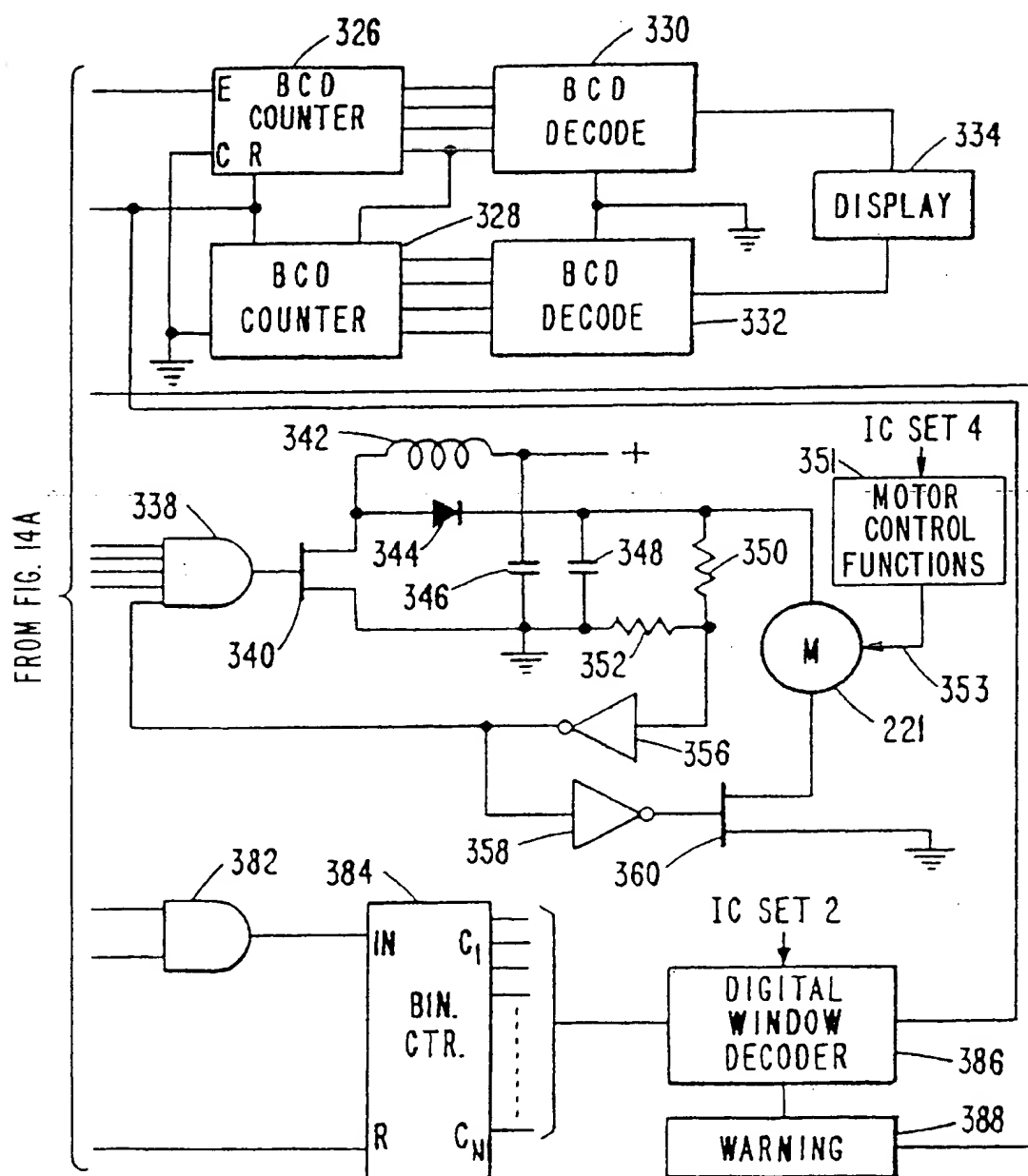


FIG. 14B

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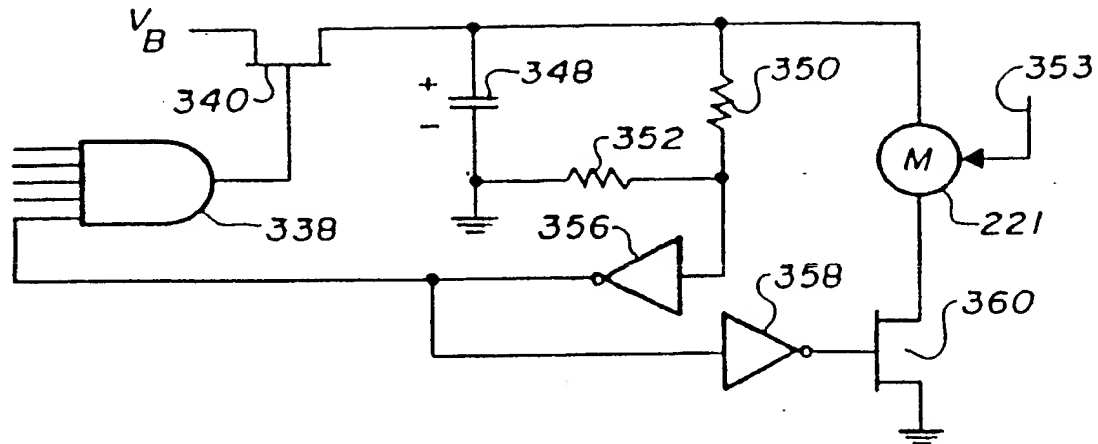


FIG. 15

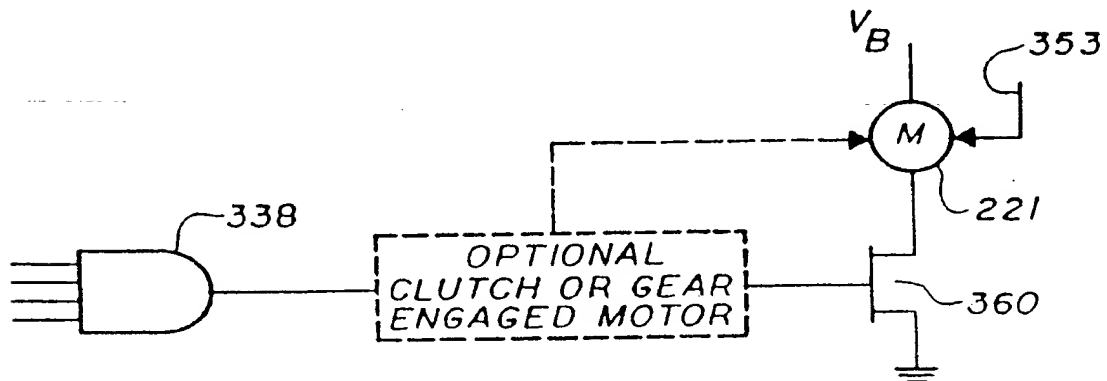


FIG. 16

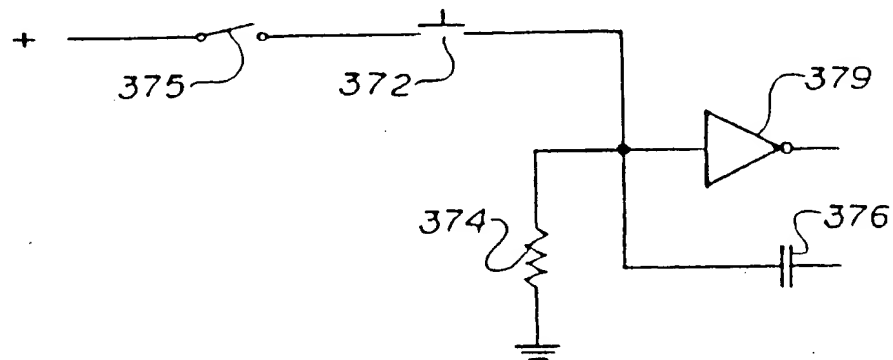
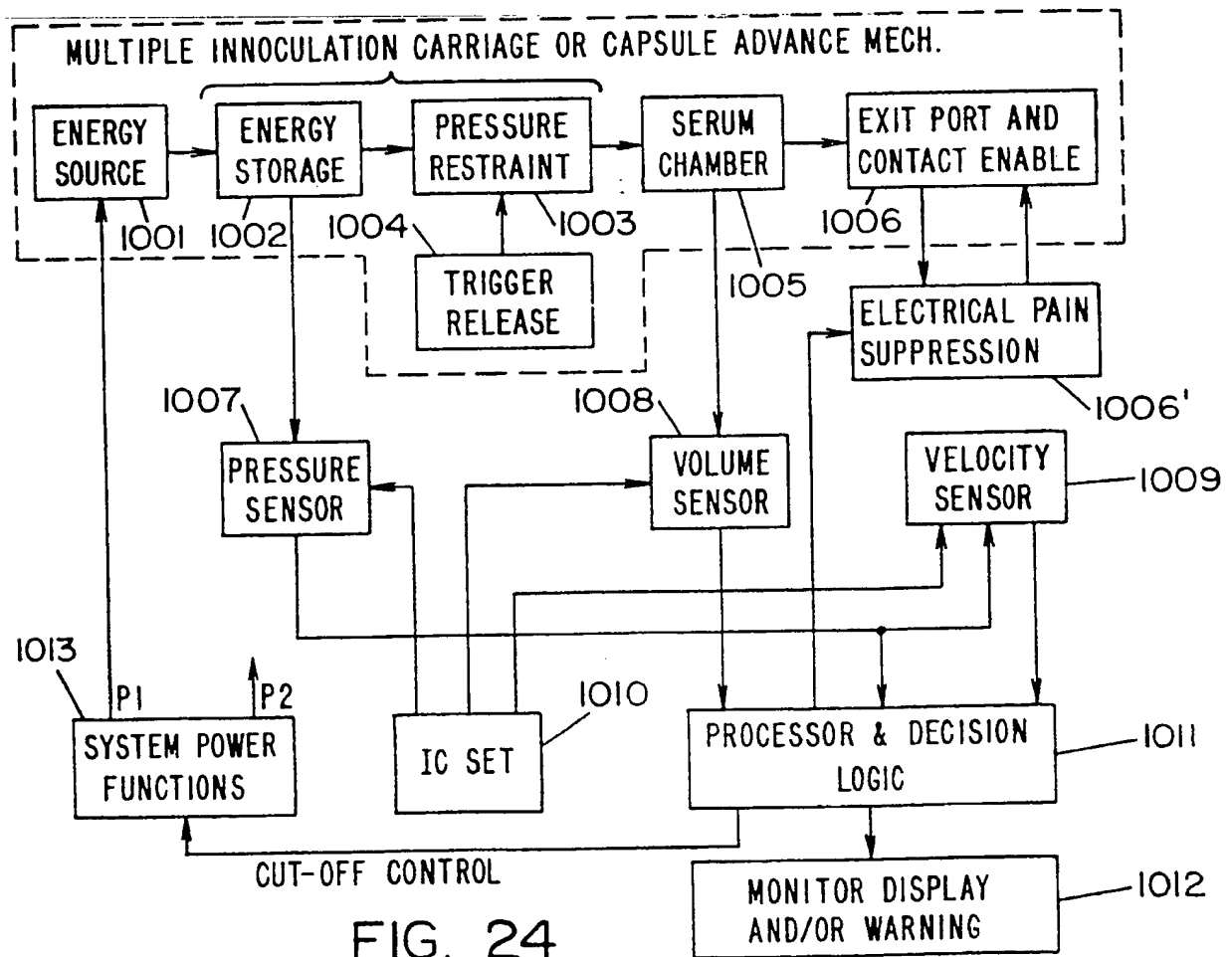
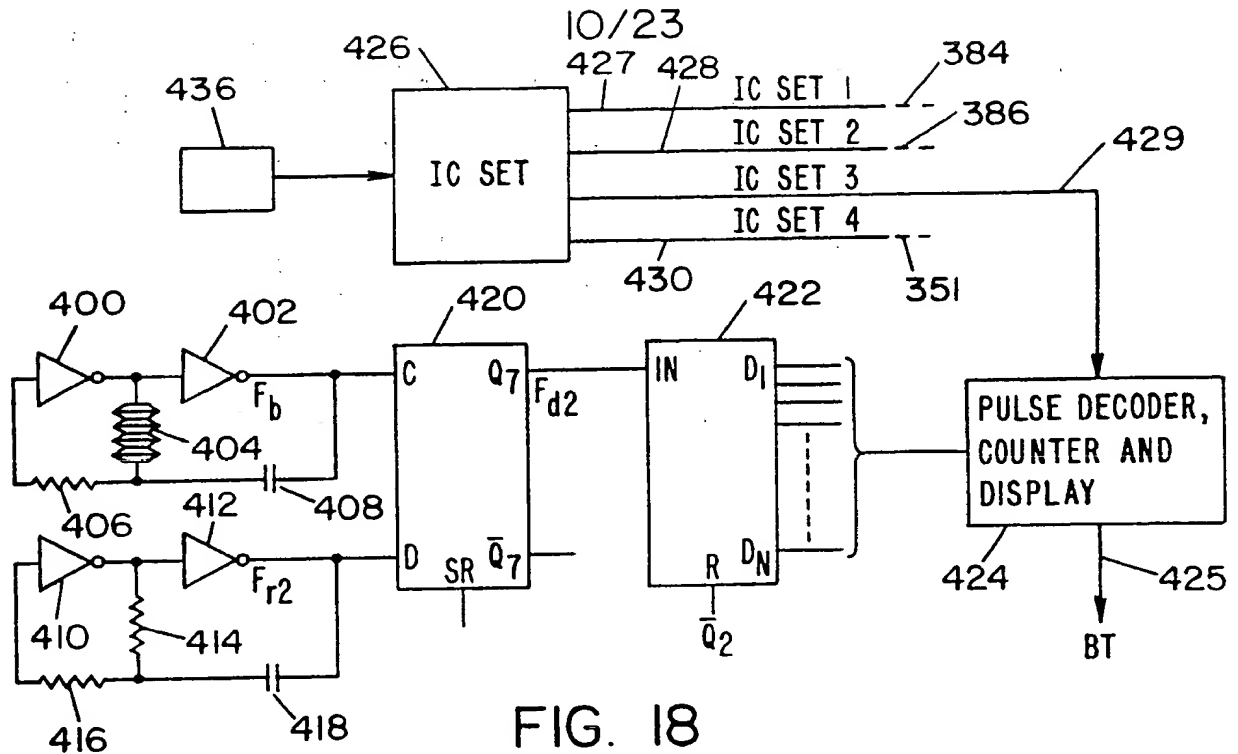
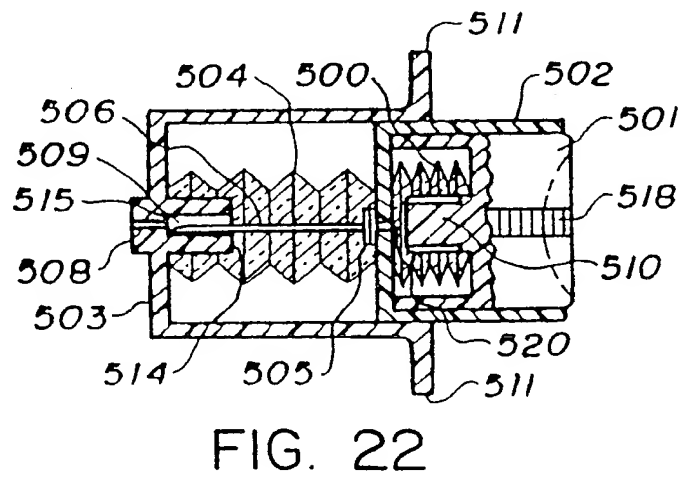
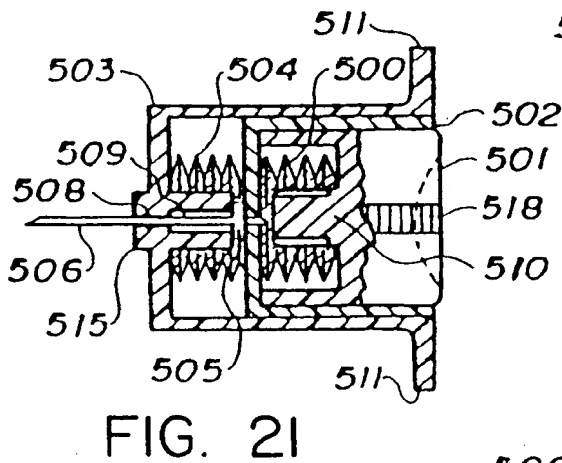
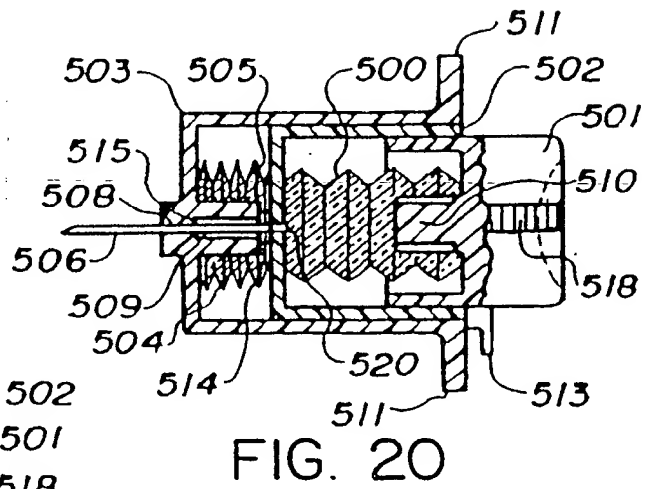
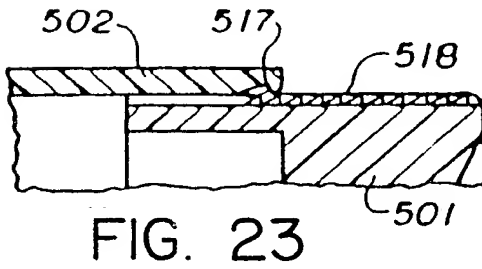
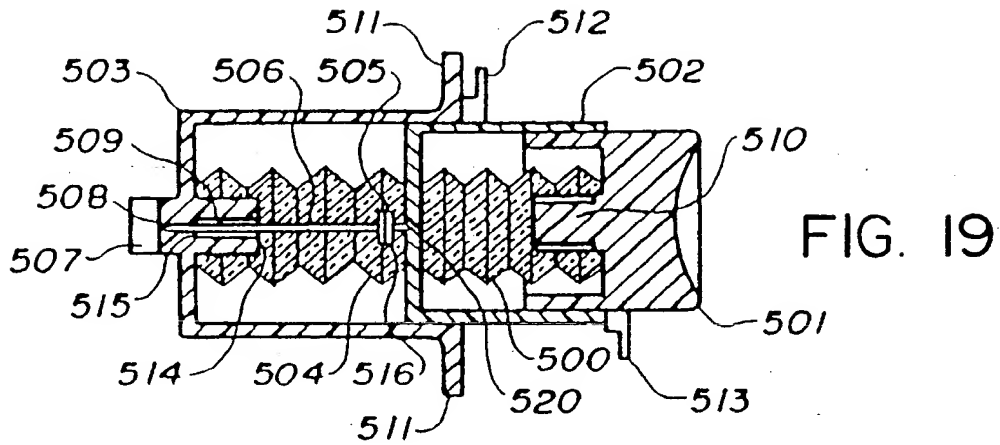


FIG. 17



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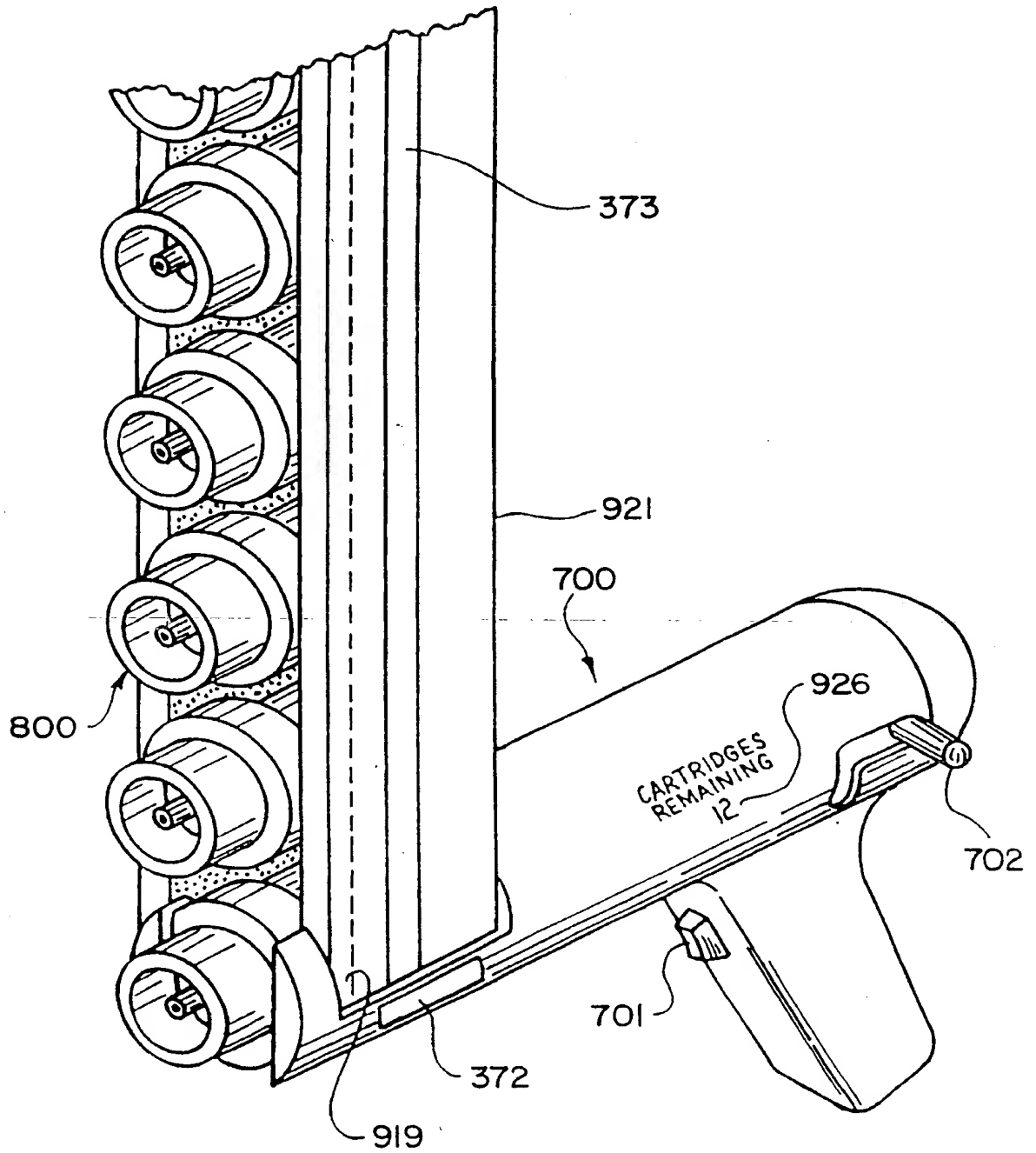


FIG. 26

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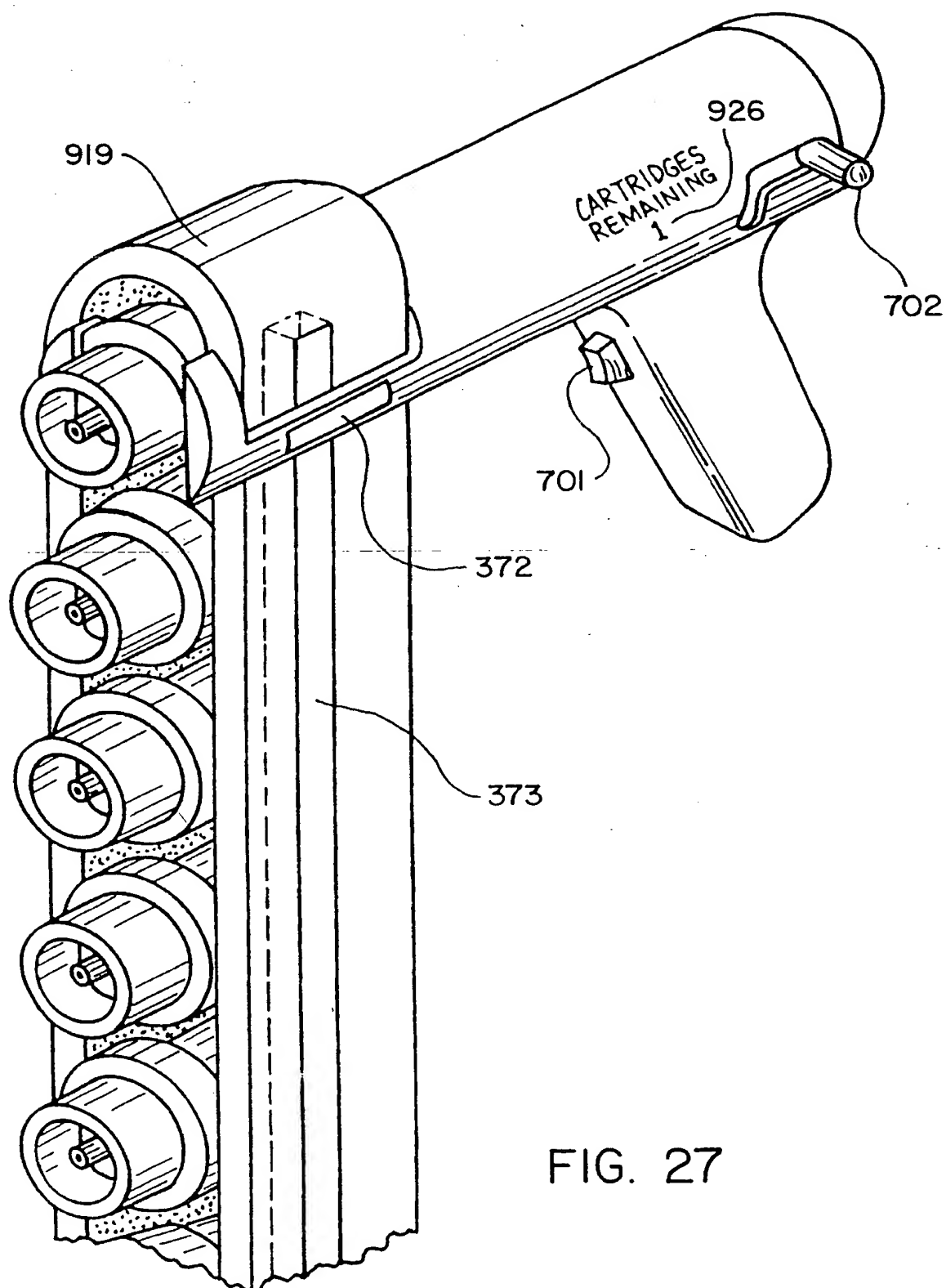


FIG. 27

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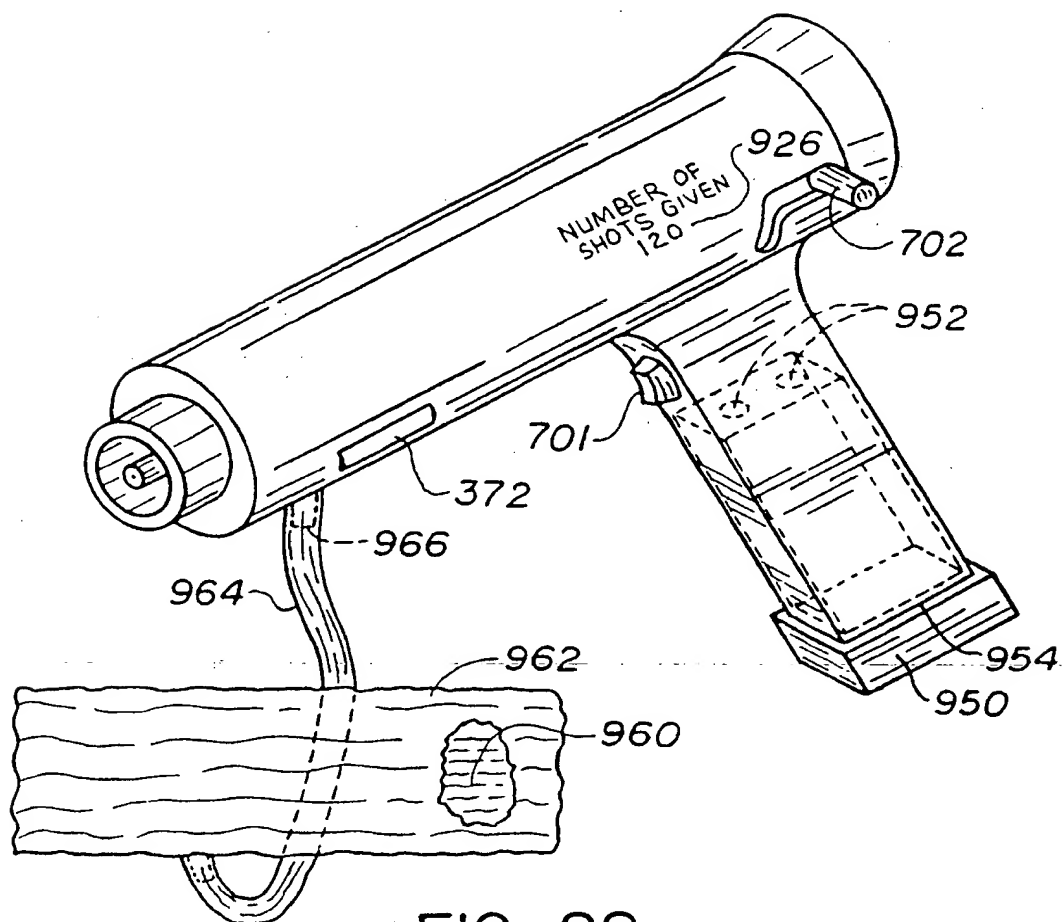


FIG. 28

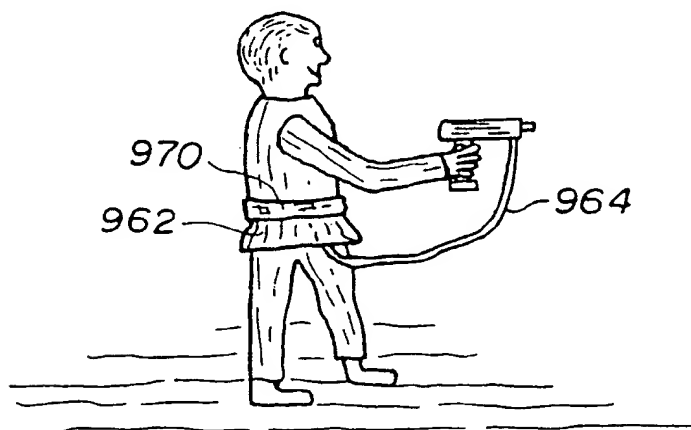
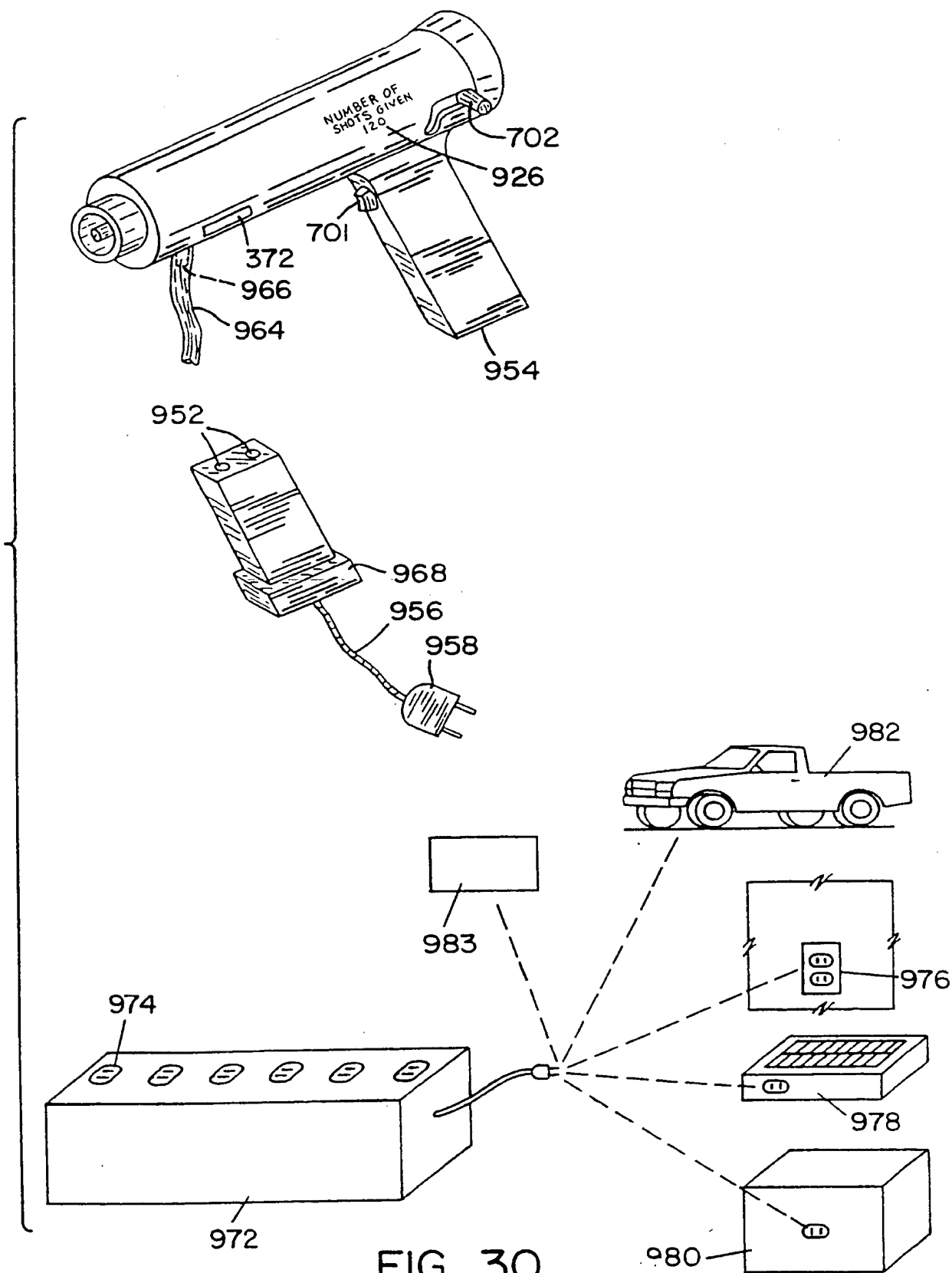


FIG. 29

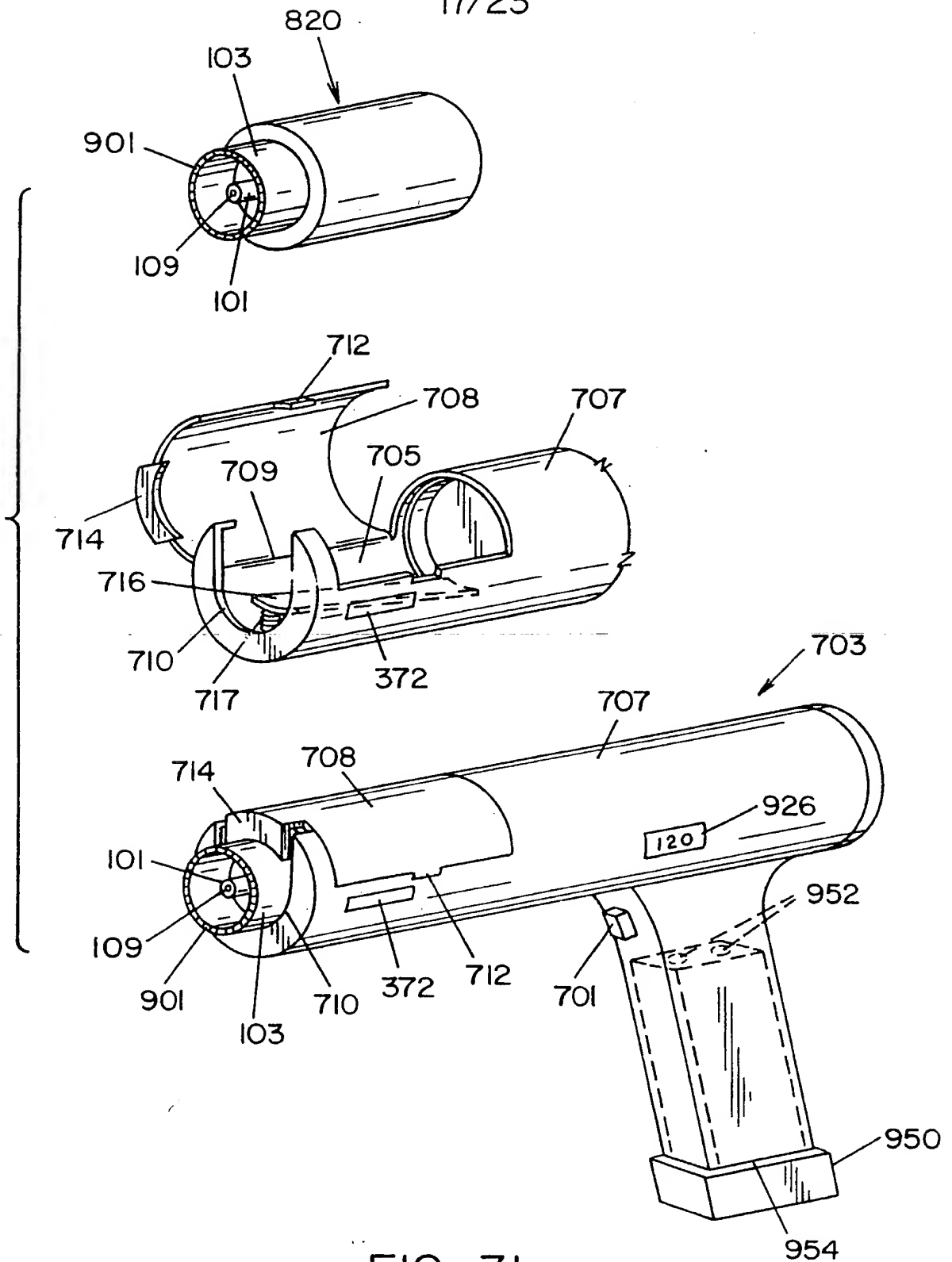
SUBSTITUTE SHEET (RULE 26)

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SUBSTITUTE SHEET (RULE 26)

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SUBSTITUTE SHEET (RULE 26)

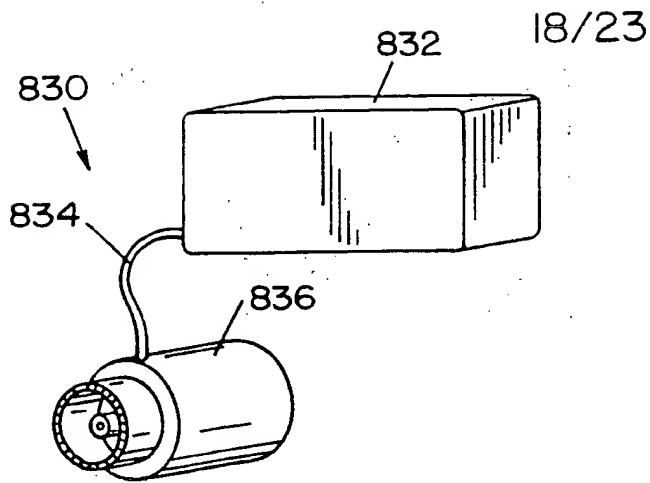


FIG. 32

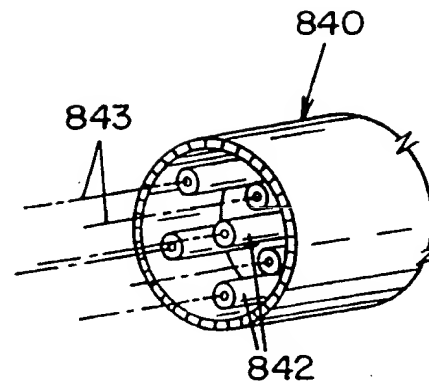


FIG. 33

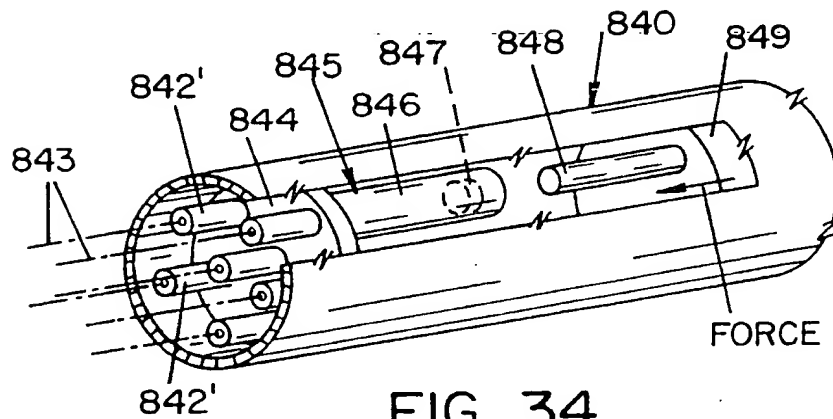


FIG. 34

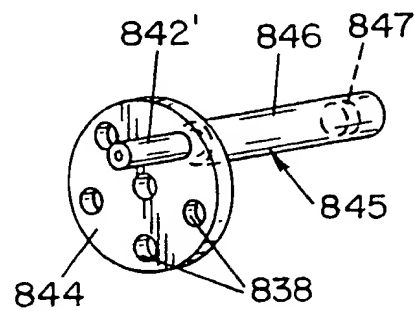


FIG. 35

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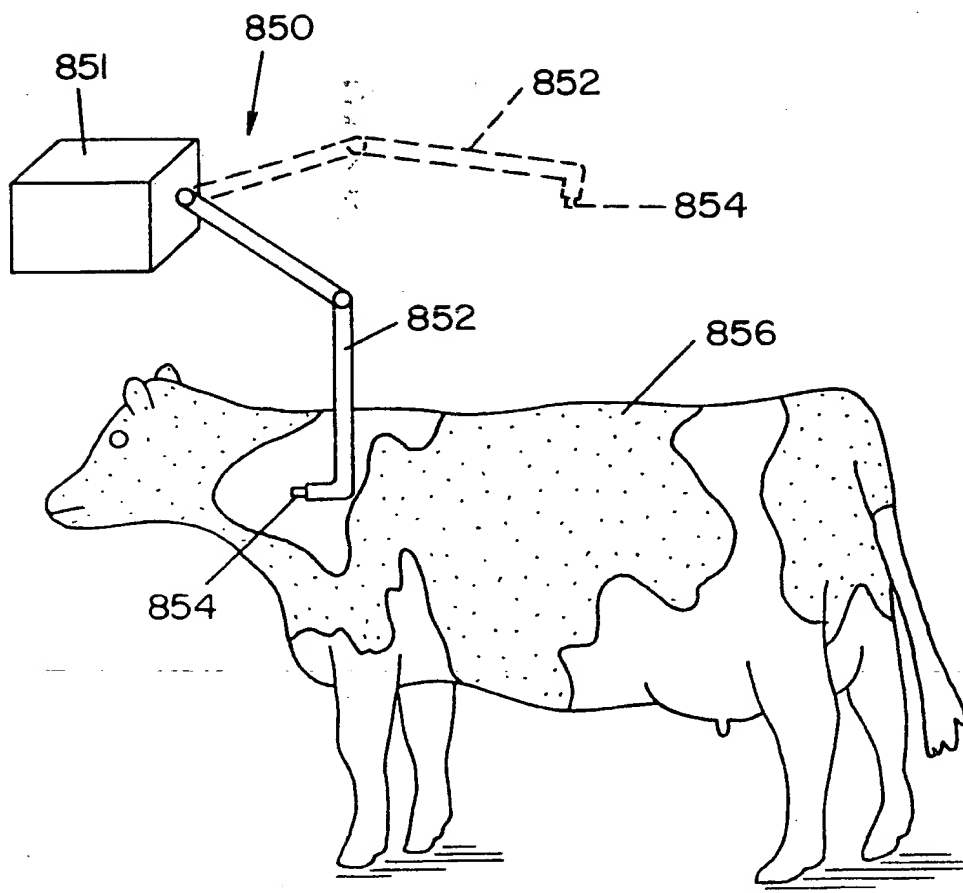


FIG. 36



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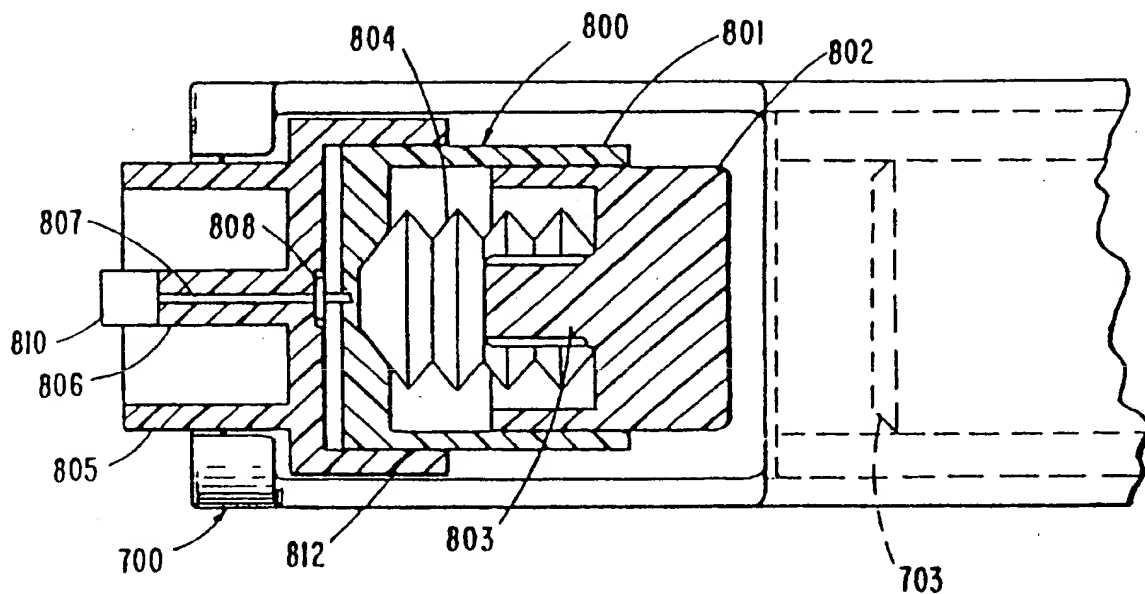


FIG. 37

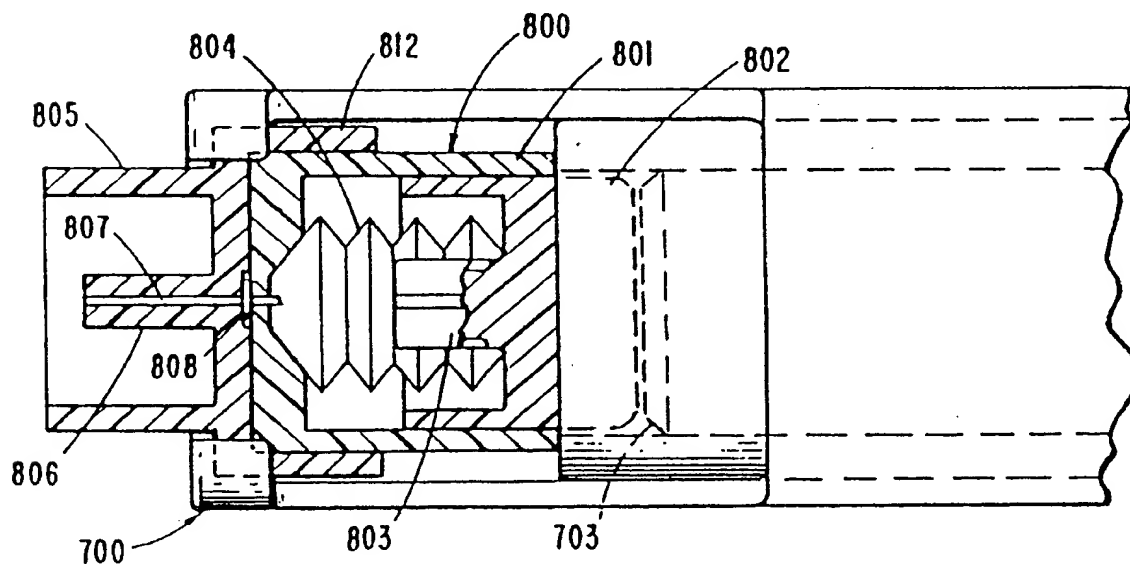


FIG. 38

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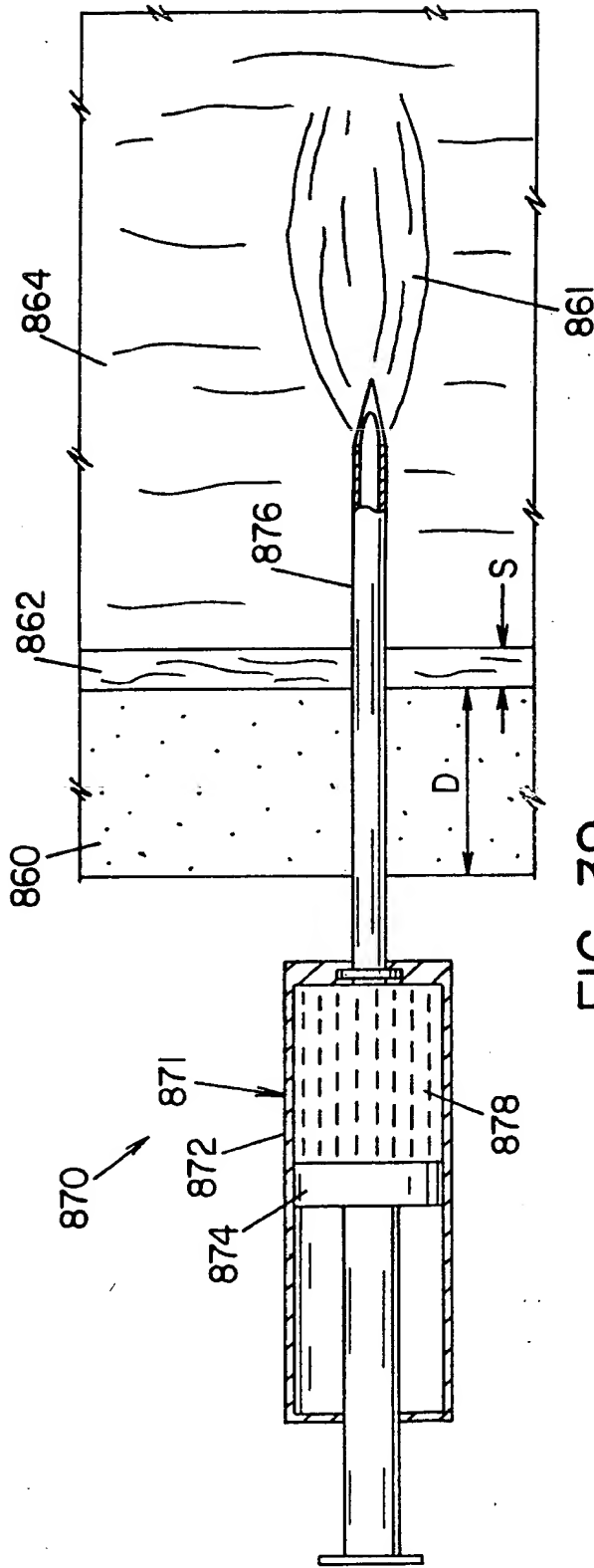


FIG. 39  
(PRIOR ART)

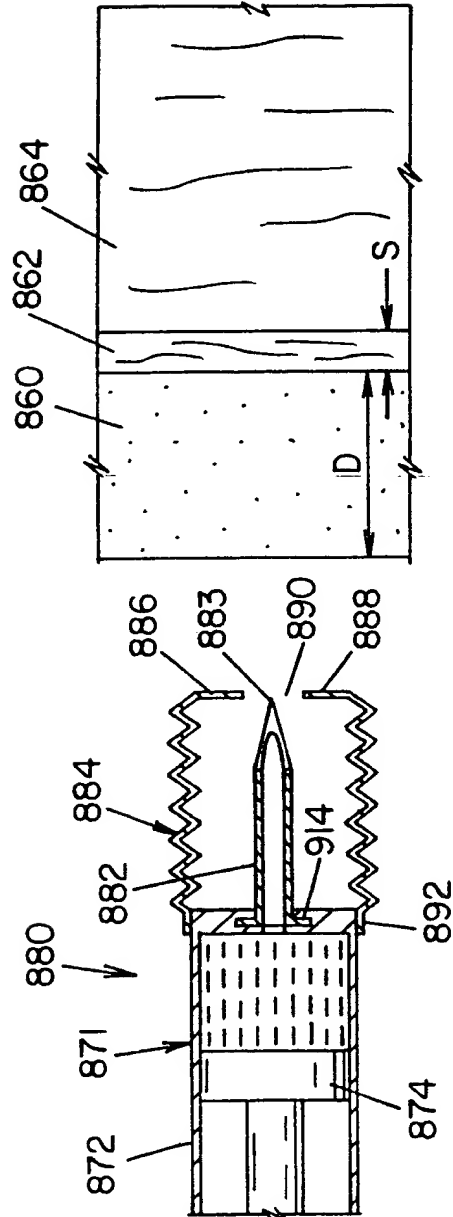


FIG. 40

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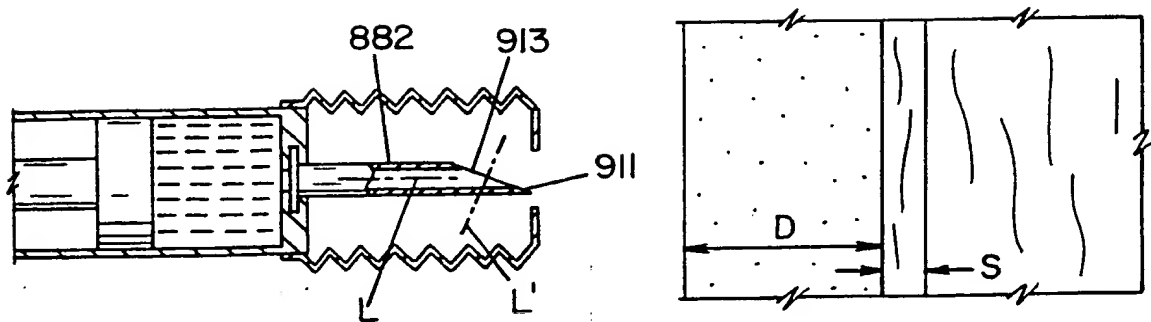


FIG. 41

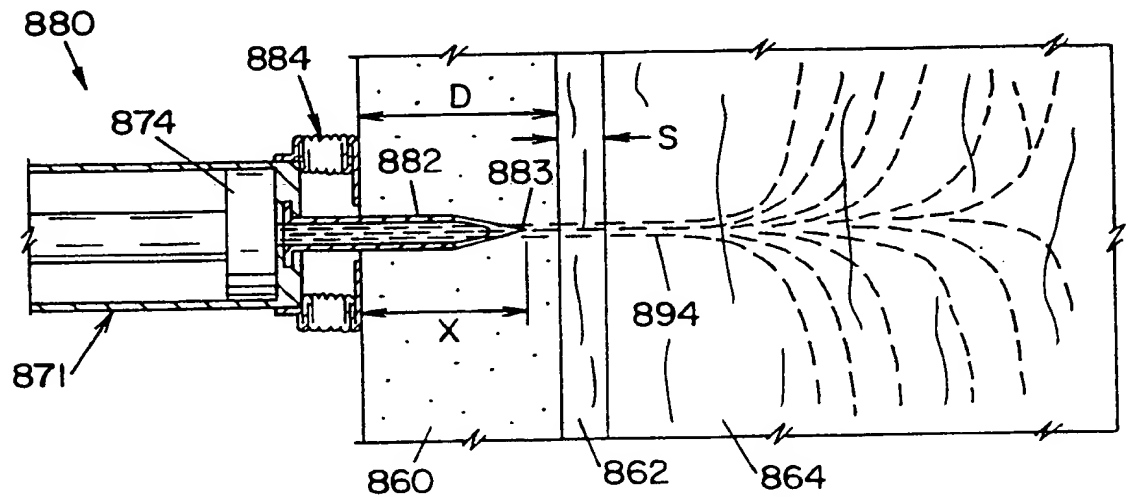


FIG. 42

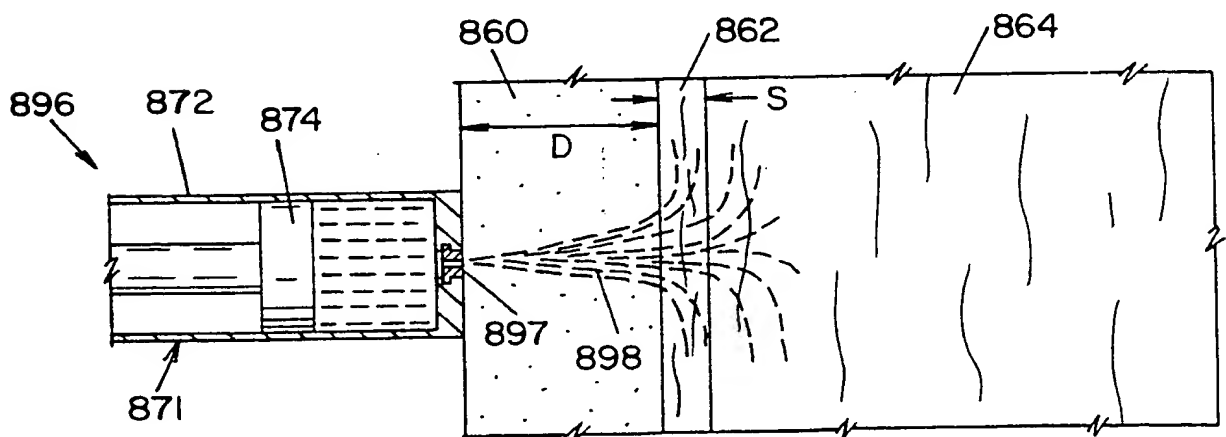


FIG. 43  
(PRIOR ART)

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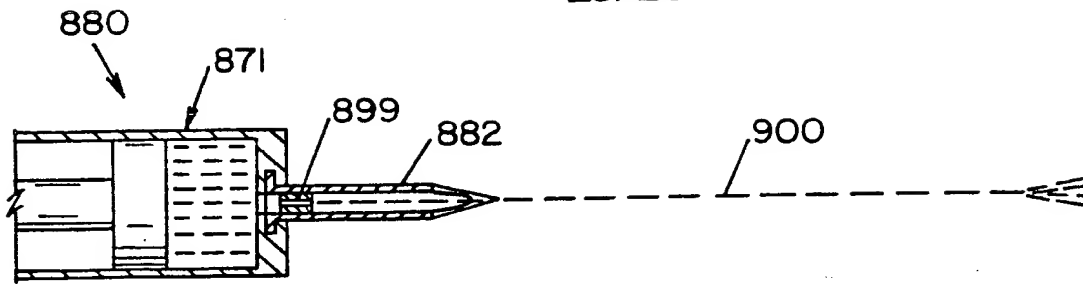


FIG. 44

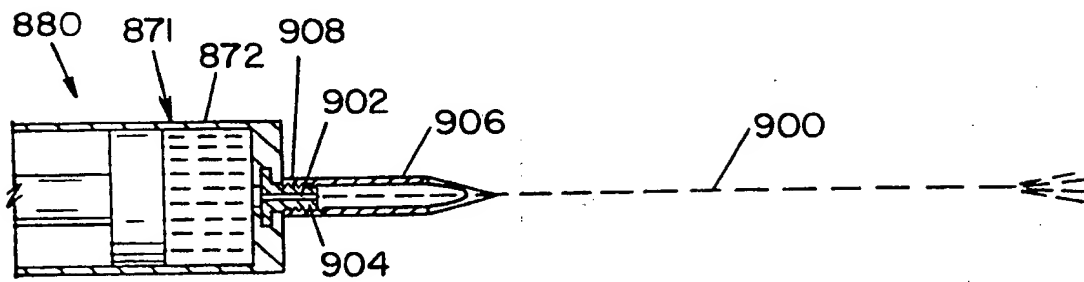


FIG. 45

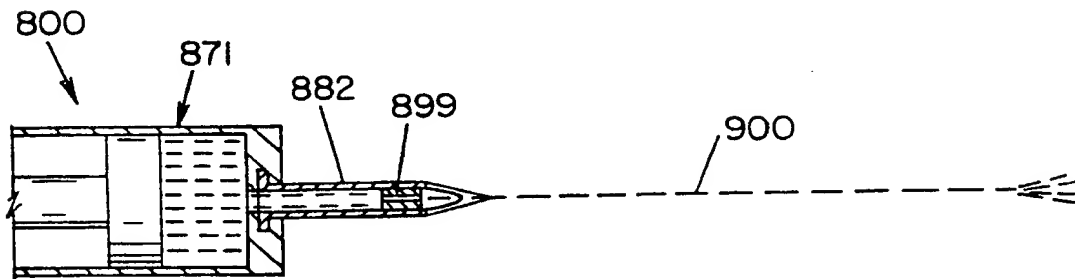


FIG. 46

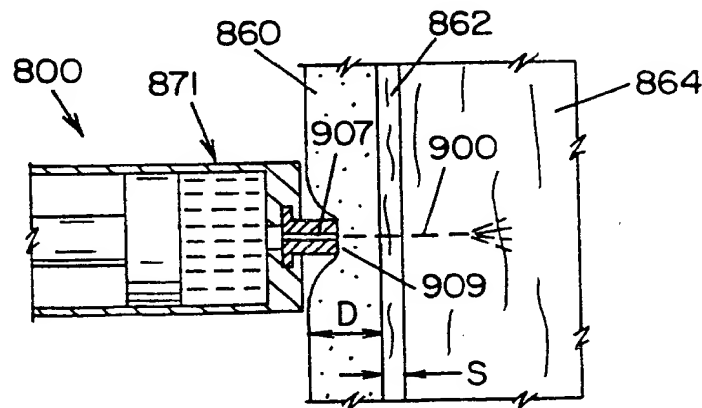


FIG. 47

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/19449

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 11/00

US CL : 604/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/68-72, 134, 137

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,430,626 A (BERGMAN) 04 March 1969, entire document.	47
Y	US 3,911,930 A (HAGFORS et al) 14 October 1975, Abstract.	67, 68
X	US 4,680,027 A (PARSONS et al) 14 July 1987, entire document.	35, 38, 39
---		-----
Y		36, 37, 40, 41
Y	SU 1584956 A (UKR VETERINARY RES) 15 August 1990, Abstract.	7, 9-11, 13-16. 26
X	US 5,026,343 A (HOLZER) 25 June 1991, entire document.	42



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*B* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

21 APRIL 1998

Date of mailing of the international search report

06 MAY 1998

Name and mailing address of the ISA/US  
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RALPH LEWIS

Telephone No. (703) 308-0770

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/19449

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,318,522 A (D'ANTONIO) 07 June 1994, entire document.	1-13, 15-24, 27, 29, 30, 32-34, 48, 49, 51, 69-72 ----- 14, 25, 26, 28, 31, 43-46, 50, 67, 68

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